This resource will be deployed with multiple subject lines and preheaders

Subject Line: Learn about a new treatment with flexible administration options
Preheader: See administration details below.

Subject Line: What do you know about this new treatment with flexible administration options?
Preheader: See interactive content below.

Subject Line: Did you know about this new product with a flexible administration option?
Preheader: Scroll below to learn more.

Subject Line: NOW APPROVED: Find out more about this new treatment option
Preheader: See administration information for this new treatment option.

Trade: KEYTRUDA® (Pembrolizumab)
Generic: Pembrolizumab
Dosage: 100 mg/4 mL (25 mg/mL) solution for IV use, single-dose vial
Indication: Adjuvant treatment

NOW APPROVED

KEYTRUDA Qlex™
(pembrolizumab and hyaluronidase-zvdx)
injection, for subcutaneous use

KEYTRUDA QLEX is approved for adjuvant treatment after resection in solid tumor indications for KEYTRUDA® (pembrolizumab) injection, for intravenous use, or in combination with other therapies

One-week initiation is the adjuvant treatment of solid patients with resect-ed stage III melanoma, stage IIB or stage IIC non-squamous cell non-small cell lung cancer, or stage IIA or stage IIB/IIC of urothelial carcinoma.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with severe hypersensitivity to pembrolizumab, pH6, hyaluronidase or any of the excipients.

Serious and Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions. A wide array of organ-specific immune-mediated adverse reactions can occur in patients (PD-1) or the programmed death ligand 1 (PD-L1) inhibitor, including PD-1 or L1-pathway blocking, immunosuppressive, immunostimulatory, or potentially treating pathological inflammation, and infusion-related or immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or life-threatening, can affect organ systems or tissues, can affect more than one organ system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Immune-mediated adverse reactions listed here may not include all possible immune-mediated or infusion-mediated adverse reactions.

Expand to See Selected Safety Information

Selected Safety Information continued below

KEYTRUDA QLEX can be administered in as little as 1 minute

IV	SC
30 minutes	1 minute
1-minute observation period	15-minute observation period
1 IV pump, 1 IV line, 1 IV needle, 1 IV dressing	1 syringe, 1 needle, 1 dressing
1 IV infusion bag	1 vial
2 IV injection needles	2 vial injection needles

Time on account of speed of injection

KEYTRUDA QLEX must be administered by healthcare provider

Tap arrows to see more.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection site options: abdomen or thigh

The 2 site area around the navel

Tap arrows to see more.

Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration schedule from KEYTRUDA
- Administer KEYTRUDA QLEX as a subcutaneous injection in the thigh or abdomen, avoiding the 5 cm area around the navel
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2 cm from a scar or other injection site
- During treatment with KEYTRUDA QLEX, do not administer KEYTRUDA at the same time as KEYTRUDA QLEX or KEYTRUDA QLEX (mixture)

Tap arrows to see more.

For the adjuvant treatment of NSCLC, Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX, or from KEYTRUDA QLEX to KEYTRUDA—at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

- Immune-mediated pneumonitis and myocarditis have been reported with PD-1 and PD-L1 inhibitor administration, including fatalities. Early identification and management are essential to ensure safe use of anti-PD-1/PD-L1 therapeutics. Monitor patients for signs and symptoms that may be consistent with pneumonitis or myocarditis. Evaluate clinically suspected pneumonitis or myocarditis with appropriate medical evaluation, including imaging and laboratory tests, to establish a diagnosis. Administer corticosteroids for severe or life-threatening pneumonitis or myocarditis, including opportunistic infections, when ruled out as appropriate.
- Immune-mediated pneumonitis: KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. In general, if pneumonitis occurs in patients in neoadjuvant or adjuvant therapy, consider a diagnosis of pneumonitis in patients presenting with signs and symptoms of radiation pneumonitis. Pneumonitis occurred in patients treated with KEYTRUDA, including Grad 5 (1.1%), Grade 3 (0.7%), and Grade 2 (2.1%) reactions. Systemic corticosteroids were required in most patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 0.7% of patients and withholding in 0.1% (20 of patients). Of patients who were evaluated for pneumonitis or pneumonitis-like signs and symptoms, 2.9% (20 of 683) underwent imaging. Pneumonitis resolved in 12 patients (60%) with follow-up imaging available. Of patients who received corticosteroids for pneumonitis, 0.7% (5 of patients) resolved after tapering corticosteroids. Pneumonitis occurred in 1.1% (12/1) of patients receiving KEYTRUDA, including Grade 2 (0.4%) and Grade 3 (0.3%) pneumonitis.
- Immune-mediated colitis: KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis. In general, if colitis occurs in patients in neoadjuvant or adjuvant therapy, consider a diagnosis of colitis in patients presenting with signs and symptoms of radiation colitis. In cases of corticosteroid-refractory immune-mediated colitis, administer infliximab after ruling out infectious etiology.
- Immune-mediated colitis occurred in 1.7% (12/1) of patients receiving KEYTRUDA, including Grade 3 (0.7%) and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in most patients. Immune-mediated colitis led to permanent discontinuation of KEYTRUDA in 0.4% of patients and withholding in 0.1% (1 of patients). All patients who were evaluated for immune-mediated colitis underwent endoscopy or imaging. Immune-mediated colitis resolved in 75% of patients with follow-up available. Of patients who were administered corticosteroids for immune-mediated colitis, 0.7% (5 of patients) resolved after tapering corticosteroids. Immune-mediated colitis occurred in 1.2% (0.2/1) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 2 (0.3%) immune reactions.

Immune-Mediated and Infusion-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in patients treated with KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.7%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in most patients. Immune-mediated hepatitis led to permanent discontinuation of KEYTRUDA in 0.6% of patients and withholding in 0.1% (1 of patients). Of patients who were evaluated for immune-mediated hepatitis, 0.3% (2 of patients). All patients who were administered corticosteroids for immune-mediated hepatitis had resolution of adverse reaction. Hepatitis resolved in 50% of patients with follow-up available. Immune-mediated hepatitis occurred in 0.1% (0/1) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.1%).

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause adrenal insufficiency (primary and secondary) which can be life-threatening in its acute presentation. Administer systemic corticosteroids, including supraphysiologic dosages of systemic corticosteroids, for at least 30 days followed by a tapering regimen for severe adrenal insufficiency. Withhold or discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in most patients. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.1% of patients and withholding in 0.1% (2 of patients). Adrenal insufficiency resolved in 0.3% (2 of patients). Of patients who were administered corticosteroids for adrenal insufficiency, 0.3% (2 of patients) resolved after tapering corticosteroids. Adrenal insufficiency occurred in 0.1% (0/1) of patients receiving KEYTRUDA, including Grade 3 (0.0%) and Grade 2 (0.1%) reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause hypophysitis. In general, if hypophysitis can present with acute symptoms associated with mass effect such as headache, purulent cerebrospinal fluid secretion, diplopia, or visual field defect, consider a diagnosis of hypophysitis. Hypophysitis can lead to hypopituitarism. Withhold or discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Hypophysitis occurred in patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in most patients. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% of patients and withholding in 0.1% (1 of patients). Hypophysitis resolved in 0.3% (2 of patients). Of patients who were administered corticosteroids for hypophysitis, 0.3% (2 of patients) resolved after tapering corticosteroids. Hypophysitis occurred in 0.1% (0/1) of patients receiving KEYTRUDA, including Grade 3 (0.0%) and Grade 2 (0.1%) reactions.

Hypothyroidism

- KEYTRUDA and KEYTRUDA QLEX can cause hypothyroidism. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement as indicated. Withhold or discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Hypothyroidism occurred in patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (3.1%) reactions. Hypothyroidism led to permanent discontinuation of KEYTRUDA in 0.1% of patients and withholding in 0.1% (1 of patients). Of patients who were administered hormone replacement, 3.2% (19 of patients) resolved. Hypothyroidism occurred in 0.8% (0/2) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.7%).
- Hypothyroidism occurred in 0.1% (0/1) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.1%). Hypothyroidism led to permanent discontinuation of KEYTRUDA in 0.1% (0/1) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.1%). Hypothyroidism resolved in 0.3% (0/1) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.1%).

Type 1 Diabetes Mellitus (DM), Where Consistent with Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.2% (0.3/1)of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Type 1 DM led to permanent discontinuation of KEYTRUDA in 0.1% of patients. All patients who were administered insulin for Type 1 DM achieved improvement. Type 1 DM occurred in 0.1% (0/1) of patients receiving KEYTRUDA in combination with chemotherapy.

Immune-Mediated Neuritis With Clinical Sarcoidosis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated neuritis.
- Immune-mediated neuritis occurred in 0.1% (0/1) of patients receiving KEYTRUDA, including Grade 3 (0.1%) reactions. Systemic corticosteroids were required in most patients. Immune-mediated neuritis led to permanent discontinuation of KEYTRUDA in 0.1% (0/1) of patients. All patients who were administered corticosteroids for immune-mediated neuritis had resolution of adverse reaction. Immune-mediated neuritis occurred in 0.1% (0/1)of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.1%).

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in patients treated with KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in most patients. Immune-mediated nephritis led to permanent discontinuation of KEYTRUDA in 0.3% of patients. All patients who were administered corticosteroids for immune-mediated nephritis had resolution of adverse reaction. Immune-mediated nephritis occurred in patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.3%) reactions.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in patients treated with anti-PD-1/PD-L1 treatments. Topical emollient and/or topical corticosteroids ointment may be sufficient to treat mild or moderate non-bullous, non-exfoliative rash. Withhold or discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatitis occurred in patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in most patients. Immune-mediated dermatitis led to permanent discontinuation of KEYTRUDA in 0.2% (1 of patients). All patients who were administered corticosteroids for immune-mediated dermatitis had resolution of adverse reaction. Immune-mediated dermatitis occurred in patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.3%).

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an unknown frequency in post-marketing use of patients who received KEYTRUDA. Based on the type of immune response, the use of other anti-PD-1/PD-L1 therapeutics, and the severity of reactions been reported for some of these adverse events, serious sequelae can be expected to occur in patients with KEYTRUDA-induced adverse reactions if not promptly recognized and appropriately managed. Immune-mediated adverse reactions listed here may not include all possible immune-mediated adverse reactions: myocarditis, myositis/polymyositis, rhabdomyolysis (and sequelae of rhabdomyolysis), myasthenia gravis (including exacerbation), Guillain-Barré syndrome, myelitis, demyelination, sequelae of cerebral inflammatory vasculitis can occur. Some cases of myocarditis have resulted in sequelae of arrhythmia, conduction disorders, and cardiomyopathy. In the majority of cases of myocarditis, resolution of myocarditis has occurred after initiation of treatment with systemic steroids to lesser doses than those recommended for corticosteroid. Pancreatitis, to include fatalities, hepatitis, including autoimmune hepatitis, nephritis, including autoimmune nephritis, Sarcoidosis, Immune-mediated enterocolitis, Immune-mediated hemolytic anemia, Aplastic anemia, Hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, Histiocytic necrosing lymphadenitis (Kikuchi lymphadenitis), Immune-mediated pancreatitis, Immune-mediated hypophysitis, Uveitis, Pancreatitis, to include fatalities, Pancreatic enzyme elevations, Immune-mediated nephritis, Renal failure, Immune-mediated dermatitis, Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), Vitiligo, Immune-mediated hypothyroidism, Immune-mediated hyperthyroidism, Immune-mediated adrenal insufficiency, Immune-mediated encephalitis, Immune-mediated myocarditis, Immune-mediated myasthenia gravis (including exacerbation of symptoms), Immune-mediated myositis, Immune-mediated rhabdomyolysis (myoglobin-induced nephropathy), Immune-mediated hemolytic anemia, Immune-mediated thrombocytopenia, Immune-mediated erythema multiforme, Immune-mediated hepatitis (including transaminitis elevations), Immune-mediated cholangitis, Sarcoidosis.

Infusion-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause infusion-related reactions, including anaphylaxis. Discontinue KEYTRUDA and KEYTRUDA QLEX for anaphylaxis. Withhold or slow rate of infusion for other infusion-related reactions. Infusion-related reactions, skin reactions and pancreatitis, occurred in patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.4%) reactions. Infusion-related reactions led to permanent discontinuation of KEYTRUDA in 0.2% of patients and withholding in 0.1% (1 of patients). Of patients who were administered corticosteroids for infusion-related reactions, 0.3% (2 of patients) resolved. Infusion-related reactions, skin reactions and pancreatitis, occurred in patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.4%) reactions.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after treatment with KEYTRUDA. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after relapsed hematologic malignancy treated with PD-1 blockade, steroid-requiring febrile pneumonitis, and infectious complications that occur after Hematopoietic Stem Cell Transplantation (HSCT). Follow patients closely for evidence of transplant-related complications and promptly initiate therapeutic interventions in accordance with applicable standards of care when an allogeneic HSCT is performed.

Increased Adverse Reactions in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, PD-1 and PD-L1 inhibitors in combination pomalyst and dexamethasone resulted in increased mortality and adverse reactions compared to pomalyst and dexamethasone alone. Fatal adverse reactions occurred in patients with multiple myeloma.

Embryo-Fetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating treatment with KEYTRUDA and KEYTRUDA QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

Lactation

- Advise women not to breast feed.

Females and Males of Reproductive Potential

- Females: KEYTRUDA: Contraception: Advise women of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying full prescribing information for KEYTRUDA and KEYTRUDA QLEX. This is not a complete list of the Selected Safety Information for KEYTRUDA QLEX that are available.

keytrudaqlex.com/isi
Ask Merck
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For assistance, please contact your **rep** or **sales representative**

Note: The information provided herein is for informational purposes only and is not intended to be a substitute for professional medical advice.

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Merck & Co., Inc., 2000 Galloping Hill Road, Kenilworth, NJ 07033, USA

USA-PEM-260001-0000

Dear:
Re: KEYTRUDA (pembrolizumab)
Subject: NOW APPROVED for treatment of female genital tract cancer

NOW APPROVED

KEYTRUDA Qlex™
pembrolizumab and hyaluronidase-zzxf
injection, 395 mg/3,200 U

KEYTRUDA QLEX is approved for use in adult patients across most indications for KEYTRUDA (pembrolizumab) injection 100 mg: whether alone or in combination with chemotherapy, with or without bevacizumab, for treatment of adult patients with recurrent or persistent or stage III or stage IV cancer of female genital tract, whose tumors express PD-L1 (CPS ≥ 1), as determined by an FDA-approved test.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to pembrolizumab or any hyaluronidase or excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

KEYTRUDA and KEYTRUDA QLEX are immunotherapy antibodies that belong to a class of immune checkpoint inhibitors. The original pembrolizumab IV formulation (KEYTRUDA) is thought to exert its effect by blocking the PD-1/PD-L1 signaling pathway, thereby inhibiting the activity of the immune response. Immune checkpoint inhibitors may be associated with immune-mediated adverse reactions. These immune-mediated adverse reactions, which may be severe or life-threatening, can occur in any organ system or tissue, and can occur at any time after starting treatment or after discontinuation of treatment. Most of these immune-mediated adverse reactions listed here may not resolve promptly if they are recognized as immune-mediated adverse reactions. Immune-mediated adverse reactions not listed here may also occur and may be more common in patients treated with immunotherapy antibodies. Immune-mediated adverse reactions reported to occurs with use of other immunotherapy antibodies include: Guillain-Barré syndrome, myasthenic syndrome, and myasthenia gravis. Depending on severity of adverse reactions, withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX, administer corticosteroids, and, if applicable, initiate hormone replacement therapy. Except for severe or life-threatening adverse reactions, consider resuming KEYTRUDA or KEYTRUDA QLEX after adverse reactions have resolved to baseline and after administration of any corticosteroids has been tapered for at least 1 month. Consider resuming KEYTRUDA or KEYTRUDA QLEX for all other adverse reactions after resolution of adverse reactions to baseline.

Colitis

Selected Safety Information continued

KEYTRUDA QLEX can be administered in less time than KEYTRUDA

KEYTRUDA	KEYTRUDA QLEX
30-minute IV infusion every 3 weeks	1-minute SC injection every 3 weeks
30-minute IV infusion every 6 weeks	1-minute SC injection every 6 weeks

Time saved per dose

"Time saved per SC vs. IV administration of KEYTRUDA, based on 30-minute IV infusion.

SC = subcutaneous; IV = intravenous.

The access to care team

For the adjusted treatment of patients who receive KEYTRUDA or KEYTRUDA QLEX, who have no disease recurrence, unacceptable toxicity, or up to 18 months.

Patients have the option to switch between KEYTRUDA and KEYTRUDA QLEX—at KEYTRUDA QLEX's or KEYTRUDA—at their next scheduled dose

For current patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care by not requiring an infusion center

Learn more about clinical trials for KEYTRUDA QLEX

Selected Safety Information (continued)

Immune-Mediated Adverse Reactions (continued)

KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening colitis. Monitor for signs and symptoms of colitis. Withhold KEYTRUDA and KEYTRUDA QLEX for grade 2 colitis. Permanently discontinue KEYTRUDA or KEYTRUDA QLEX for grade 3 or 4 colitis. Administer corticosteroids and, if applicable, initiate hormone replacement therapy. Except for severe or life-threatening adverse reactions, consider resuming KEYTRUDA or KEYTRUDA QLEX after adverse reactions have resolved to baseline and after administration of any corticosteroids has been tapered for at least 1 month. Consider resuming KEYTRUDA or KEYTRUDA QLEX for all other adverse reactions after resolution of adverse reactions to baseline.

Colitis occurred in 1.1% (20/1780) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.7%), Grade 4 (0.1%), and Grade 5 (0.1%) colitis. Colitis occurred in 1.1% (20/1) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.1%) colitis

MONDAY, OCTOBER 7, 2024

Please share this information with other members of your practice who prescribe or dispense KEYTRUDA.

From: Medical Information
To: **SAMPLE** Healthcare
Subject: KEYTRUDA QLEX (pembrolizumab and hyaluronidase-zzxh) subcutaneous injection

NOW APPROVED

KEYTRUDA QLEX®
pembrolizumab and hyaluronidase-zzxh
subcutaneous injection

KEYTRUDA QLEX is approved for use in adult patients with solid tumors or adult and pediatric patients with cHL for subcutaneous injection. Only administer alone or in combination with other therapies.

Consult prescribing information and other resources for complete information on KEYTRUDA QLEX, an intravenous (IV) pembrolizumab formulation, and other KEYTRUDA formulations.

Selected Safety Information

Contraindications

- KEYTRUDA QLEX is contraindicated in patients with severe hypersensitivity to pembrolizumab, hyaluronidase-zzxh, hyaluronidase or any excipients.

Severe and Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which may involve any organ system or tissue, may occur in patients treated with KEYTRUDA. Immune-mediated adverse reactions usually manifest during treatment, but can also manifest after discontinuation of KEYTRUDA. Immune-mediated adverse reactions can be severe and fatal. Immune-mediated adverse reactions in patients treated with KEYTRUDA in combination with other therapies may be more frequent, severe, and prolonged than those in patients treated with KEYTRUDA alone. Immune-mediated adverse reactions may mimic those of other chronic inflammatory diseases. Immune-mediated adverse reactions can involve any organ system or tissue and include the following:
  - Immune-mediated pneumonitis: Monitor patients for signs and symptoms of pneumonitis. Evaluate suspected cases of pneumonitis with appropriate imaging. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) pneumonitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) pneumonitis. In patients with severe pneumonitis who have partial or no response to corticosteroids, consider other immunosuppressants. Withhold KEYTRUDA in patients with Grade 2 pneumonitis. In patients with Grade 2 pneumonitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after pneumonitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated colitis: Monitor patients for signs and symptoms of colitis. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) colitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) colitis. In patients with Grade 2 colitis, consider other immunosuppressant therapy in addition to corticosteroids. Withhold KEYTRUDA in patients with Grade 2 colitis. In patients with Grade 2 colitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after colitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hepatitis and hepatitis with elevated transaminases or total bilirubin: Monitor patients for abnormal liver function. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hepatitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hepatitis. In patients with Grade 2 hepatitis with total bilirubin greater than 1.5 times to 3 times the upper limit of normal (ULN) or transaminases greater than 3 to 5 times the upper limit of normal (ULN), withhold KEYTRUDA. In patients with Grade 2 hepatitis with total bilirubin greater than 3 times to 5 times ULN or transaminases greater than 5 to 8 times ULN, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hepatitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated nephritis with renal dysfunction: Monitor patients for abnormal renal function. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) nephritis with renal dysfunction. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) nephritis with renal dysfunction. In patients with Grade 2 nephritis with renal dysfunction who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after nephritis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated endocrinopathies: Monitor patients for signs and symptoms of endocrinopathy. Administer hormone replacement therapy as needed. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) endocrinopathy. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) endocrinopathy. In patients with Grade 2 endocrinopathy who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after endocrinopathy has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hypophysitis: Monitor patients for signs and symptoms of hypophysitis. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hypophysitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hypophysitis. In patients with Grade 2 hypophysitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hypophysitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated adrenal insufficiency: Monitor patients for signs and symptoms of adrenal insufficiency. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) adrenal insufficiency. In patients with Grade 2 adrenal insufficiency who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after adrenal insufficiency has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hyperglycemia: Monitor patients for signs and symptoms of hyperglycemia. Administer insulin for severe (Grade 3) or life-threatening (Grade 4) hyperglycemia. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hyperglycemia. In patients with Grade 2 hyperglycemia who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hyperglycemia has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hypothyroidism: Monitor patients for signs and symptoms of hypothyroidism. Administer hormone replacement therapy as needed. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hypothyroidism. In patients with Grade 2 hypothyroidism who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hypothyroidism has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hyperthyroidism: Monitor patients for signs and symptoms of hyperthyroidism. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hyperthyroidism. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hyperthyroidism. In patients with Grade 2 hyperthyroidism who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hyperthyroidism has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated myasthenia gravis, myositis, myocarditis, and myelitis: Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) myasthenia gravis, myositis, myocarditis, and myelitis. In patients with Grade 2 myasthenia gravis, myositis, myocarditis, and myelitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after myasthenia gravis, myositis, myocarditis, and myelitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated vasculitis: Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) vasculitis. In patients with Grade 2 vasculitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after vasculitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Immune-mediated hemolytic anemia: Monitor patients for signs and symptoms of hemolytic anemia. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hemolytic anemia. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hemolytic anemia. In patients with Grade 2 hemolytic anemia who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hemolytic anemia has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
  - Other immune-mediated adverse reactions: The following immune-mediated adverse reactions occurred at a frequency of less than 1% in patients treated with KEYTRUDA monotherapy: Guillain-Barré syndrome, facial and abducens nerve paresis, encephalitis, demyelination, sarcoidosis, uveitis, iridocyclitis, chorioretinitis, pancreatitis, including fatal cases, exocrinopathy, arthritis, rheumatic disorders, dermatomyositis, rhabdomyolysis, myocarditis, pericarditis, vasculitis, Stevens-Johnson syndrome, autoimmune anemia, autoimmune thrombocytopenia, myelitis, and myasthenic syndrome. Depending on the affected organ, these events could manifest as, but are not limited to, the following: Grade 2 uveitis, Grade 3 adrenal insufficiency, Grade 3 myelitis, and Grade 3 myasthenic syndrome.

Selected Safety Information (continued below)

KEYTRUDA QLEX can be administered in as little as 1 minute

IV	SC
pembrolizumab	**pembrolizumab and hyaluronidase-zzxh**
30 min	1 min
IV administration[1]	**SC administration**[1]

[1] Pembrolizumab administered every 3 weeks. Adapted from Kim TW, et al.[1]

KEYTRUDA QLEX can be administered in as little as 1 minute

Selected Safety Information (continued below)

Give your patients a choice of where you administer their treatment

KEYTRUDA QLEX subcutaneous injection site options:
- Abdomen (preferred)
- Thigh
- Upper arm

Important Dosage and Administration information

- KEYTRUDA QLEX has different dosage and administration information than intravenous KEYTRUDA
- Administer KEYTRUDA QLEX as a single-dose injection only, subcutaneously in abdomen, anterior thigh, or upper arm
- Inject into healthy skin and avoid injection into areas that are tender, bruised, or scarred
- Ensure the injection site is at least 2.5 cm from a mole or tattoo
- Only pembrolizumab with hyaluronidase-zzxh is approved for subcutaneous injection; do not use pembrolizumab alone SC
- Do not administer KEYTRUDA QLEX IV

For the adjuvant treatment of HCC: Treatment with KEYTRUDA QLEX should commence within 1 month of completion of adjuvant therapy, if applicable, or up to 12 months from randomization

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX, or from KEYTRUDA QLEX to KEYTRUDA, at their next scheduled dose

For cancer patients, treatment with KEYTRUDA QLEX may be flexible, or as little as 1 day, depending on efficacy and safety

Learn more about KEYTRUDA QLEX dosing for HCC

Selected Safety Information (continued)

Immune-Mediated Colitis

- KEYTRUDA and PEGPH20 (SC) with chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (1.1%), Grade 3 (0.7%), and Grade 4 (0.2%) colitis, in addition to corticosteroids, administer immunosuppressant therapy. Withhold KEYTRUDA in patients with Grade 2 colitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) colitis. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after colitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.
- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (0.7%), Grade 3 (0.3%), and Grade 4 (0.3%) colitis, in addition to corticosteroids, administer immunosuppressant therapy. Withhold KEYTRUDA in patients with Grade 2 colitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) colitis. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after colitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Hepatitis and Hepatitis with Elevated Transaminases or Total Bilirubin

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (0.7%), Grade 3 (0.3%), and Grade 4 (0.3%) hepatitis, in addition to corticosteroids, administer immunosuppressant therapy. Withhold KEYTRUDA in patients with Grade 2 hepatitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hepatitis. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hepatitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (0.2%), Grade 3 (0.3%), and Grade 4 (0.1%) nephritis with renal dysfunction, in addition to corticosteroids, administer immunosuppressant therapy. Withhold KEYTRUDA in patients with Grade 2 nephritis with renal dysfunction. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) nephritis with renal dysfunction. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after nephritis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Endocrinopathies

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) adrenal insufficiency, Grade 3 (0.1%) hypophysitis, hypothyroidism and Grade 3 (0.1%) hyperthyroidism, administer hormone replacement therapy as needed. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) endocrinopathy. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) endocrinopathy. In patients with Grade 2 endocrinopathy who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after endocrinopathy has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Other Immune-Mediated Adverse Reactions

- Monitor patients for hypoglycemia in patients treated with KEYTRUDA and PEGPH20 (SC) and chemotherapy. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) myasthenic syndrome, Guillain-Barré syndrome, and myelitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) myasthenic syndrome, Guillain-Barré syndrome, and myelitis. In patients with Grade 2 myasthenic syndrome, Guillain-Barré syndrome, and myelitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after myasthenic syndrome, Guillain-Barré syndrome, and myelitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Severe Infusion Reactions

- Monitor patients for hypoxia and infusion reactions. Interrupt the infusion for severe (Grade 3) infusion reactions. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) infusion reactions. Systemic corticosteroids have been used in addition to H1 and H2 antagonists, acetaminophen, and epinephrine in clinical trials of KEYTRUDA and other PD-1 receptor blockade-containing products. Consider premedication with H1 and H2 antagonists, acetaminophen, and non-dihydropyridine calcium channel blockers for infusions of other products that have caused severe infusion reactions.

Severe Cutaneous Adverse Reactions

- Monitor patients for signs and symptoms of severe cutaneous adverse reactions. Depending on the severity of the adverse reaction, withhold or permanently discontinue KEYTRUDA. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) severe cutaneous adverse reactions. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) severe cutaneous adverse reactions. In patients with severe cutaneous adverse reactions who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after severe cutaneous adverse reactions has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Embryo-Fetal Toxicity

- Based on its mechanism of action, fetal harm is expected when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating KEYTRUDA. Advise women of reproductive potential to use effective contraception during treatment with KEYTRUDA and for 4 months after the last dose of KEYTRUDA.

Adverse Reactions

- In the KN-522 trial, the most common adverse reactions (≥20%) in patients who received a single dose of KEYTRUDA in combination with chemotherapy followed by KEYTRUDA monotherapy were anemia (62%), alopecia (51%), fatigue (46%), nausea (41%), neutropenia (35%), constipation (29%), vomiting (25%), and decreased appetite (20%). The most common adverse reactions (≥20%) in patients who received KEYTRUDA monotherapy were musculoskeletal pain (22%), fatigue (21%), and rash (20%). The most common adverse reactions (≥20%) in patients who received KEYTRUDA and PEGPH20 (SC) in combination with chemotherapy were anemia (72%), neutropenia (47%), nausea (43%), fatigue (41%), diarrhea (38%), vomiting (31%), constipation (29%), decreased appetite (28%), and alopecia (20%). The most common adverse reactions (≥20%) in patients who received KEYTRUDA and PEGPH20 (SC) in combination with monotherapy were musculoskeletal pain (32%), fatigue (29%), and rash (25%).

Hepatitis and Hepatitis with Elevated Transaminases or Total Bilirubin

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (0.7%), Grade 3 (0.3%), and Grade 4 (0.3%) hepatitis, hepatitis with total bilirubin greater than 1.5 times to 3 times the upper limit of normal (ULN) or transaminases greater than 3 to 5 times the upper limit of normal (ULN), including Grade 2 (0.3%), Grade 3 (0.3%), and Grade 4 (0.3%) hepatitis with total bilirubin greater than 3 times to 5 times ULN or transaminases greater than 5 to 8 times ULN, in addition to corticosteroids, administer immunosuppressant therapy. Withhold KEYTRUDA in patients with Grade 2 hepatitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hepatitis. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hepatitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Hypophysitis

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 2 (0.2%), Grade 3 (0.1%) and Grade 4 (0.1%) hypophysitis, hypophysitis can follow immune-mediated adrenal insufficiency, which may be life-threatening. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hypophysitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hypophysitis. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hypophysitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Adrenal Insufficiency

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) adrenal insufficiency, administer hormone replacement therapy as needed. Administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) adrenal insufficiency. In patients with Grade 2 adrenal insufficiency who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after adrenal insufficiency has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Hyperglycemia

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.3%) and Grade 4 (0.3%) hyperglycemia, administer insulin for severe (Grade 3) or life-threatening (Grade 4) hyperglycemia. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hyperglycemia. In patients with Grade 2 hyperglycemia who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hyperglycemia has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Hypothyroidism

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hypothyroidism, administer hormone replacement therapy as needed. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hypothyroidism. In patients with Grade 2 hypothyroidism who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hypothyroidism has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Hyperthyroidism

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hyperthyroidism, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hyperthyroidism. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hyperthyroidism. In patients with Grade 2 hyperthyroidism who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hyperthyroidism has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Other Immune-Mediated Adverse Reactions

- The following immune-mediated adverse reactions occurred at a frequency of less than 1% in patients treated with KEYTRUDA monotherapy: Guillain-Barré syndrome, facial and abducens nerve paresis, encephalitis, demyelination, sarcoidosis, uveitis, iridocyclitis, chorioretinitis, pancreatitis, including fatal cases, exocrinopathy, arthritis, rheumatic disorders, dermatomyositis, rhabdomyolysis, myocarditis, pericarditis, vasculitis, Stevens-Johnson syndrome, autoimmune anemia, autoimmune thrombocytopenia, myelitis, and myasthenic syndrome. Depending on the affected organ, these events could manifest as, but are not limited to, the following: Grade 2 uveitis, Grade 3 adrenal insufficiency, Grade 3 myelitis, and Grade 3 myasthenic syndrome.

Immune-Mediated Myasthenic Syndrome/Myasthenia Gravis/Myositis/Myocarditis/Myelitis

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) myasthenic syndrome/myasthenia gravis, Grade 3 (0.1%) myositis, Grade 3 (0.1%) myocarditis, and Grade 3 (0.1%) myelitis, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis. In patients with Grade 2 myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Vasculitis

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) vasculitis, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) vasculitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) vasculitis. In patients with Grade 2 vasculitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after vasculitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Immune-Mediated Hemolytic Anemia

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) immune-mediated hemolytic anemia, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hemolytic anemia. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) immune-mediated hemolytic anemia. In patients with Grade 2 immune-mediated hemolytic anemia who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after immune-mediated hemolytic anemia has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Other Adverse Reactions

- The following adverse reactions occurred at a frequency of less than 1% in patients treated with KEYTRUDA monotherapy: Guillain-Barré syndrome, facial and abducens nerve paresis, encephalitis, demyelination, sarcoidosis, uveitis, iridocyclitis, chorioretinitis, pancreatitis, including fatal cases, exocrinopathy, arthritis, rheumatic disorders, dermatomyositis, rhabdomyolysis, myocarditis, pericarditis, vasculitis, Stevens-Johnson syndrome, autoimmune anemia, autoimmune thrombocytopenia, myelitis, and myasthenic syndrome. Depending on the affected organ, these events could manifest as, but are not limited to, the following: Grade 2 uveitis, Grade 3 adrenal insufficiency, Grade 3 myelitis, and Grade 3 myasthenic syndrome.

Immune-Mediated Adverse Reactions in Combination Therapy Trials

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) immune-mediated hemolytic anemia, Grade 3 (0.1%) myasthenic syndrome/myasthenia gravis, Grade 3 (0.1%) myositis, Grade 3 (0.1%) myocarditis, and Grade 3 (0.1%) myelitis, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hemolytic anemia, myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) immune-mediated hemolytic anemia, myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis. In patients with Grade 2 immune-mediated hemolytic anemia, myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after immune-mediated hemolytic anemia, myasthenic syndrome/myasthenia gravis, myositis, myocarditis, and myelitis has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Contraindications

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients with known severe hypersensitivity to PEGPH20 or any component of the formulation, or severe anaphylactic reactions to polysorbate 80 or to any other biologics administered in combination with KEYTRUDA and PEGPH20 (SC) and chemotherapy.

Hypersensitivity

- KEYTRUDA and PEGPH20 (SC) and chemotherapy: In patients treated with KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hypersensitivity, administer corticosteroids for severe (Grade 3) or life-threatening (Grade 4) hypersensitivity. Permanently discontinue KEYTRUDA in all cases of Grade 3 or life-threatening (Grade 4) hypersensitivity. In patients with Grade 2 hypersensitivity who show no improvement within 4 weeks of corticosteroid therapy, permanently discontinue KEYTRUDA. In patients who show improvement with corticosteroids, consider tapering corticosteroids and resuming KEYTRUDA after hypersensitivity has improved to Grade 1 or less. Upon resumption of corticosteroid therapy, consider prophylactic antimicrobials for opportunistic infections in patients at high risk.

Lymphopenia

- Lymphopenia was observed in various clinical trials of KEYTRUDA, including Grade 3 (2.1%) and Grade 4 (0.3%) lymphopenia in 2,799 patients with various cancers treated with KEYTRUDA monotherapy.

Refer to the KEYTRUDA QLEX Prescribing Information and accompanying Prescribing Information for KEYTRUDA and PEGPH20 (SC) for complete information on Selected Safety Information.

Learn more

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For prescribers: please click here for video inserts and more information.

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NOW APPROVED

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Solution/Injection | 50 mg + 2,000 units/mL

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA® (pembrolizumab) Injection 100 mg—whether alone or in combination with other therapies

One such indication is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA QLEX and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.

Expand to See Selected Safety Information

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
9 MEDS	9 MEDS
pembrolizumab 200 mg and berahyaluronidase alfa 4,000 units	pembrolizumab 400 mg and berahyaluronidase alfa 8,000 units
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

**Does not account for all aspects of treatment. Actual clinic time may vary.*

KEYTRUDA QLEX must be administered by a healthcare provider.

Tap arrows to see more.

1 / 3

For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX—or KEYTRUDA QLEX to KEYTRUDA—at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti-PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of immune-mediated adverse reactions. Withhold KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer high-dose corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (94/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of the 94 patients with pneumonitis, Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (13/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.1% (46/2799) of patients receiving KEYTRUDA, including Grade 4 (0.2%), Grade 3 (0.4%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 89% (33/46); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.3% (10) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (2/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of the 19 patients with immune-mediated hepatitis, Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (5/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, pituitarytha, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.9% (19/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (1/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (5.2%). Hypothyroidism occurred in 14% (35/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

Type 1 Diabetes Mellitus (DM), Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.2% (6/2799) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti-PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.8% (4/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti-PD-1/PD-L1 treatments: Severe or fatal cases have been reported for some of these adverse reactions. Cardiac/Vascular: Myocarditis, pericarditis, vasculitis. Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy. Ocular: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various ophthalmologic manifestations of uveitis, blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss. Gastrointestinal: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis (2.8%), duodenitis. Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.1%), polymyalgia rheumatica. Endocrine: Hypophysitis, diabetes insipidus, autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi-Fujimotodisease), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (6/201) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (2.5%) and Grade 3 (0.5%). Interrupt injection (if not already fully administered) and resume if symptoms resolve for mild or moderate systemic reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT prior to or after beginning therapy with a PD-1/PD-L1 blocking antibody. These include hyperacute graft-versus-host disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti-PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly. Consider the benefit vs risks of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti-PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. In females of reproductive potential, verify pregnancy status prior to initiating KEYTRUDA or KEYTRUDA QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- In study MK-3475A-077, when KEYTRUDA QLEX was administered with chemotherapy versus chemotherapy alone, and long-term follow-up, Adverse reactions occurred in 99% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), pancitrin (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 21% of patients. Adverse reactions which required permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 40% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥25%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 25% of patients receiving KEYTRUDA, the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 2.4% of patients, of these, pneumonitis occurred with KEYTRUDA due to adverse reactions occurred in 0.2% of 489 patients, the most common (≥1%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (22%), and hypothyroidism (21%).

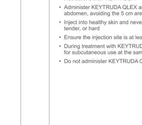
Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options:
thigh or abdomen, avoiding the 5 cm area around the navel



Tap arrows to see more.

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Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA
- Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2.5 cm from the previous injection site
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same time as KEYTRUDA QLEX
- Do not administer KEYTRUDA QLEX intravenously

Tap arrows to see more.

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keytrudahcp.com/qlex

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pembrolizumab + berahyaluronidase alfa-pmph
50 mg/2 mL (25 mg/1 mL) Solution

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for which KEYTRUDA (pembrolizumab) injection 100 mg—whether alone or in combination with other therapies

One such indication is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and metastasectomy

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

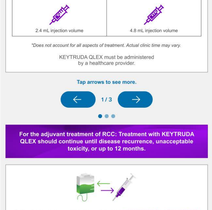
Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance induced by immune checkpoint pathways. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can affect more than one body system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early assessment and management of suspected immune-mediated adverse reactions to PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, taper corticosteroid to a dose equivalent to 10 mg daily prednisone and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Collapse

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute



Does not account for all aspects of treatment. Actual clinic time may vary.

KEYTRUDA QLEX must be administered by a healthcare provider.

Tap arrows to see more.

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For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX—or KEYTRUDA—at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early assessment and management are essential to ensure safe use of anti-PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients have received prior thoracic radiotherapy. Immune-mediated pneumonitis occurred in 3.4% (842/798) patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (839/6) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.1% (9/798) of patients. Of the 9 (0.1%) patients, All patients resolved with corticosteroid administration. Of the 9 (0.1%) patients, All patients were withheld reinitiated KEYTRUDA after symptom improvement; of these, 22% had recurrence. Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (130/2613) of patients receiving KEYTRUDA in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (2.5%) adverse reactions.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.7% (46/2708) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 72% (33/46) of patients. Immune-mediated colitis resulted in permanent discontinuation of KEYTRUDA in 0.5% (13) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, 10 patients (77%) had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (32/5) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 1.7% (192/759) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 71% (136/192) of patients. Immune-mediated hepatitis resulted in permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (12/51) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2708) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (1) and withholding in 0.4% (11) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (20/1017) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2739) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 100% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypophysitis occurred in 0.4% (2/521) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/2708) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hypothyroidism occurred in 9.8% (262/2708) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (8.8%). It led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.7% (18) of patients. Hypothyroidism resulted in permanent KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (232/2796) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (12/51) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.4%). Hypothyroidism occurred in 8% (204/2613) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (2.2%). Hyperthyroidism occurred in 14% (20/137) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (11%).

Type 1 Diabetes Mellitus, Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.2% (6/2696) of patients receiving KEYTRUDA. One patient discontinued in <0.1% (1) and withheld in 0.2% (5) of patients. KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Ophthalmic Disease

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated ophthalmic. Evaluate eosinophilia, Stevens-Johnson syndrome, dry eye with exacerbation and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti-PD-1/PD-L1 treatments. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Immune-mediated ophthalmic disease occurred in 0.8% (20/2708) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.7%) adverse reactions. Systemic corticosteroids were required in 60% (12/20) of patients. Immune-mediated ophthalmic disease resulted in permanent discontinuation in 0.1% (2) and withholding in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, 31% had recurrence. The reactions resolved in 79% of the 28 patients. Immune-mediated ophthalmic disease occurred in 0.4% (2/521) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti-PD-1/PD-L1 treatments. Severe or fatal cases have been reported for some of these adverse reactions: Cardiac/Vascular: Myocarditis, pericarditis, vasculitis; Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; Ocular: Uveitis, iritis and other inflammatory ocular disorders, including sarcoidosis, can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; Gastrointestinal: Pancreatitis, to include elevations in serum amylase and lipase levels, gastritis, duodenitis, Musculoskeletal and Connective Tissue: Myositis/ polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.5%), polymyalgia rheumatica; Endocrine: Hypoparathyroidism; Hematologic/Immune: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, Grade 3 or Grade 4 hypersensitivity or administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Infusion-related reactions have been reported in 0.2% (7/2739) patients receiving KEYTRUDA, interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (85/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (2.4%) reactions. Premedication and already fully administered and recent if symptoms recur or worsen. Monitor for infusion-related reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti-PD-1/PD-L1 treatments. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti-PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients who receive anti-PD-1/PD-L1 treatments prior or subsequent to allogeneic HSCT for signs and symptoms of these complications, and intervene promptly. Consider the benefit-to-risk of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti-PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. Verify pregnancy status in females of reproductive potential prior to initiating KEYTRUDA or already fully administered and recent if symptoms recur or worsen. Advise female reproductive partners. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti-PD-1/PD-L1 treatments. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti-PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients who receive anti-PD-1/PD-L1 treatments prior or subsequent to allogeneic HSCT for signs and symptoms of these complications, and intervene promptly. Consider the benefit-to-risk of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti-PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. Verify pregnancy status in females of reproductive potential prior to initiating KEYTRUDA or already fully administered and recent if symptoms recur or worsen. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were anemia (5%), thromboembolism (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.8%), rash (1.2%), respiratory failure (1.2%), and urinary tract infection (1.2%). Serious adverse reactions occurred in 10% of patients including pneumonitis (3.2%), metastasis sepsis (2%), death not due to adverse reaction (1.6%), and respiratory failure (1.6%). Fatal adverse reactions occurred in 4% of patients including pulmonary embolism (0.4%), cardiorespiratory arrest (0.4%), and seizure (0.4%). KEYTRUDA QLEX permanently discontinued due to an adverse reaction in 16% of 237 patients. Adverse reactions which led to permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonitis and musculoskeletal pain (2% each). In study MK-3475A-D77, when KEYTRUDA QLEX was discontinued in 40% of patients, the most common adverse reactions which required discontinuation in ≥2% of patients included neoplasms, anemia, thromboembolism, pneumonitis, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA. The serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonitis, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.4% of patients due to cardiorespiratory arrest. Permanent discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 498 patients; the most common (31%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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KEYTRUDA Qlex®
pembrolizumab + hyaluronidase-zimv 394 mg/10 mg/mL

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA® (pembrolizumab) injection 100 mg—whether alone or in combination with other therapies

One such indication is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to bevfanalimab or any component or to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA QLEX KEYTRUDA QLEX can cause immune-mediated adverse reactions. These adverse reactions may involve any organ system or tissue, can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here do not include all possible severe and fatal immune-mediated adverse reactions.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti-PD-1/PD-L1 therapies. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA QLEX KEYTRUDA QLEX is withheld, corticosteroids administered intravenously or orally for corticosteroid therapy (1 to 2 mg/kg prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Selected Safety information continues below:

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
1 vial (2 mL)	1 vial (2 mL)
pembrolizumab 394 mg and hyaluronidase-zimv 10 mg	pembrolizumab 394 mg and hyaluronidase-zimv 10 mg
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

**Does not account for all aspects of treatment. Actual clinic time may vary*

KEYTRUDA QLEX must be administered by a healthcare provider.

Selected Safety Information *(continued)*

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (342/9708) patients receiving KEYTRUDA, including Mild (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 0.9% (77/8720) of patients, and KEYTRUDA was permanent discontinued of KEYTRUDA in 1.3% (38) and withheld permanently in 0.9% (26) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, none had recurrence. Fatal pneumonitis occurred in 0.6% (18) patients. Immune-mediated pneumonitis occurred in 5% (13/261) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grad (0.4%), Grade 3 (2%), and Grade 2 (2.3%) adverse reactions.

Selected Safety Information continues below.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options: thigh or abdomen, avoiding the 5 cm area around the navel

Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA.
- Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel.
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2.5 cm from the previous injection site
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same time as KEYTRUDA QLEX
- Do not administer KEYTRUDA QLEX intravenously

For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX—or KEYTRUDA QLEX to KEYTRUDA—at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(continued)*

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.1% (96/8708) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 0.8% (72/8708) of patients, and KEYTRUDA was permanent discontinued of KEYTRUDA in 0.5% (13) and withheld in 0.5% (13) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, 22% had recurrence. Colitis resolved in 85% of the 68 patients. Immune-mediated colitis occurred in 1.2% (33/5) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatitis and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (192/29) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (131/192) of patients; additional immunosuppressant therapy was required in 19% (37) of patients. Of the patients who received systemic corticosteroids, 73% (95/131) had improvement or resolution of the adverse reaction. Of patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, none had recurrence. Hepatitis resolved in 79% (24) of the 30 patients. Immune-mediated hepatitis occurred in 0.4% (1/261) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2708) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the adverse reaction improved or resolved in 59% (10) of patients who received systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or manage of hypothyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.8% (192/708) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hypothyroidism occurred in 3.4% (96/2708) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement. Hypothyroidism resolved in 23% (22) of the 96 patients. Hypothyroidism occurred in 2.3% (6/261) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.8%) adverse reactions.
- Hyperthyroidism occurred in 1.1% (32/2708) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.7% (17) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement. Hyperthyroidism resolved in 78% (25) of the 32 patients. Hyperthyroidism occurred in 2.3% (6/261) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in 0.3% (29/708) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (69/10) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti-PD-1/PD-L1 antibodies. Manifestations of these immune-mediated dermatologic adverse reactions vary in clinical presentation and severity. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatologic adverse reactions occurred in 1.4% (362/708) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 89% (69/10) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Hypophysitis and Uveitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti-PD-1/PD-L1 antibodies. Manifestations of these immune-mediated dermatologic adverse reactions vary in clinical presentation and severity. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatologic adverse reactions occurred in 1.4% (362/708) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 89% (69/10) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld nonfatal KEYTRUDA after symptom improvement, of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Pancreatitis

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of less than 1% in patients who received KEYTRUDA or KEYTRUDA QLEX, or were reported with the use of other anti-PD-1/PD-L1 therapies: Severe or fatal cases have been reported for some of these adverse reactions. Cardiac Vascular: Myocarditis, pericarditis, vasculitis. Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy, Guillain-Barré syndrome, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require systemic steroids to prevent permanent vision loss. Gastrointestinal: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, Musculoskeletal and Connective Tissue Disorders: Myositis/polymyositis, rhabdomyolysis (and associated sequelae including renal failure), arthritis (1.1%), polymyalgia rheumatica. Endocrine: Hypophysitis/pituitary inflammation, Hemoglobin Hemolytic anemia, aplastic anemia, hemoglobinopathy lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including stomal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening hypersensitivity-related reactions, including hypersensitivity and anaphylaxis. Risk KEYTRUDA and KEYTRUDA QLEX. Monitor for signs and symptoms of hypersensitivity-related adverse reactions. Hypersensitivity-related reactions including rash, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA, Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Premedication, monitoring for hypersensitivity, and prophylactic administration of antihistamines and acetaminophen for subsequent infusions with pembrolizumab. Severe infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA, Interrupt or slow the rate of infusion for Grade 3 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Premedication, monitoring for hypersensitivity, and prophylactic administration of antihistamines and acetaminophen for subsequent infusions with pembrolizumab. Severe infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA, Interrupt or slow the rate of infusion for Grade 3 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Premedication, monitoring for hypersensitivity, and prophylactic administration of antihistamines and acetaminophen for subsequent infusions with pembrolizumab.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti-PD-1/PD-L1 treatments. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and severe liver toxicity, bone marrow toxicity, infection, and steroid-requiring febrile pneumonitis. These complications may occur despite intervening between PD-1/PD-L1 blockade and allogeneic HSCT. Consider the risk of these complications in patients who plan to undergo allogeneic HSCT. Consider the benefit vs risks of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti-PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. Verify the pregnancy status of females of reproductive potential prior to the start of KEYTRUDA or KEYTRUDA QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- In study MK-3475A-077, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 38% of patients. Serious adverse reactions in 31% of patients who received KEYTRUDA QLEX in combination with platinum and fluoropyrimidine chemotherapy, including neutropenia (12%), febrile neutropenia (2%), anemia (2%), diarrhea (1.5%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonitis (3.2%), respiratory failure (2%), death not otherwise specified (1.5%), respiratory failure (1.2%), peritonitis (0.4%), pneumonia (0.4%), and sepsis (0.4%). Adverse reactions leading to permanent discontinuation of KEYTRUDA or KEYTRUDA QLEX were permanently discontinued due to an adverse reaction in 16% of 261 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in 10% of patients included pneumonitis and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 49% of patients. Adverse reactions which resulted in dosage interruption in 10% of patients included pneumonitis, pneumonia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (53%), fatigue (51%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of recurrence receiving KEYTRUDA, the serious adverse reactions (17%) were acute kidney injury, adrenal insufficiency, pneumonitis, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 2.2% including 2 cases of pneumonitis. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common adverse reactions resulting in discontinuation were fatigue (2%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX are available.

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