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2. Opdivo

# Opdivo

**Pronunciation:** *op-DEE-voh*

**Generic name:** [nivolumab](#)

**Dosage form:** injection for intravenous infusion (10 mg/mL)

**Drug class:** [Anti-PD-1 and PD-L1 monoclonal antibodies \(immune checkpoint inhibitors\)](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Apr 15, 2025.

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## What is Opdivo?

Opdivo is used to treat many cancers, such as melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, colorectal cancer, liver cancer, esophageal squamous cell carcinoma, gastric cancer, and gastroesophageal junction cancer. It is given as an intravenous infusion (infusion into your vein; IV) over 30 minutes, every 2 to 4 weeks, depending on the type of cancer you have.

Opdivo is not chemotherapy, it is an immunotherapy treatment that can be used by itself, with chemotherapy, or with other immunotherapy treatments, such as [Yervoy](#), another checkpoint inhibitor. Opdivo targets the PD-1 protein, while Yervoy targets the CTLA-4 protein.

Opdivo first gained FDA approval in 2014. There is no generic or biosimilar.

## Mechanism

Opdivo works by interfering with the growth and spread of cancer cells in the body through a process called immune checkpoint inhibition.

- Normally, cancer cells can evade the immune system by expressing proteins called PD-L1 (programmed death-ligand 1) on their surface, which bind to PD-1 receptors on T cells.
- When PD-L1 binds to PD-1, it sends a "stop" signal to T cells, preventing them from attacking the cancer cells - essentially creating an "off switch" for the immune response.
- Opdivo is a monoclonal antibody that specifically blocks the PD-1 receptors on T cells, preventing this binding from occurring.
- By blocking this interaction, Opdivo removes the "brake" on the immune system, allowing T cells to recognize and attack cancer cells.

This reactivation of the immune response can lead to tumor shrinkage and improved survival in patients with certain types

of cancer, including melanoma, lung cancer, renal cell carcinoma, and various other malignancies.

Clinical trials have shown most people respond to Opdivo within 2-3 months of starting treatment (see [How long does Opdivo take to work?](#)). The effectiveness of Opdivo varies depending on the cancer type and stage and other factors (see [How effective is Opdivo?](#)).

## Opdivo Vs Opdivo Qvantig

[Opdivo Qvantig](#) is a formulation of Opdivo that contains hyaluronidase, which allows it to be given under the skin (subcutaneously) over 3 to 5 minutes, instead of intravenously over 30 minutes.

- Opdivo Qvantig offers faster administration but has more restricted approved uses.
- See [Opdivo Vs Opdivo Qvantig: What is the difference?](#) for more information.

## FDA Approvals and Indications

Opdivo is FDA-approved to treat the following cancers, either alone or in combination with other treatments such as Yervoy (ipilimumab):

- Melanoma
- Bladder cancer (urothelial carcinoma)
- Cancer of the stomach and esophagus
- Classical Hodgkin lymphoma (cHL)
- Colorectal cancer
- Gastric cancer, gastroesophageal junction cancer, and esophageal cancer
- Kidney cancer (renal cell carcinoma)
- Malignant pleural mesothelioma (cancer that affects the lining of the lungs and chest wall)
- Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, including cases that have progressed following prior treatment for metastatic disease
- Non-small cell lung cancer (NSCLC)
- Squamous cell cancer of the head and neck
- Unresectable or metastatic hepatocellular carcinoma (HCC), the most common primary liver cancer.

For some cancers, such as melanoma and colorectal cancer, Opdivo is approved for children aged 12 years and older. See the [Opdivo Prescribing Information](#) for a full list of indications and eligibility criteria.

Opdivo is sometimes given only if laboratory testing shows specific genetic markers or DNA mutations associated with your cancer.

Clinical trials have shown Opdivo and Yervoy work better when taken together for some types of cancer (see [How effective are Opdivo and Yervoy when taken together?](#)).

## Side effects

The **most common** side effects of Opdivo when used alone are:

- nausea, vomiting, stomach pain, loss of appetite, diarrhea, constipation;
- mouth sores, altered sense of taste;
- itching, rash, redness, or blisters on your hands or feet;
- hormonal problems;
- liver problems;
- numbness, tingling, or burning pain in your hands or feet;
- fever, body aches;
- feeling weak, tired, or short of breath;
- cold symptoms such as runny or stuffy nose, cough, sore throat;
- headache, dizziness, increased blood pressure; or
- weight loss.

The most common side effects of Opdivo and Yervoy in combination are:

- constipation
- cough
- decreased appetite
- decreased weight
- diarrhea
- dizziness
- feeling tired
- fever
- headache
- itching
- low thyroid hormone levels (hypothyroidism)
- nausea
- pain in muscles, bones, and joints
- rash
- shortness of breath
- stomach-area (abdominal) pain
- upper respiratory tract infection
- vomiting.

## Serious side effects and warnings

Opdivo can cause serious, sometimes life-threatening, side effects in many different parts of your body. Some side effects may need to be treated with other medicines, and your cancer treatments may be delayed.

**Immune system problems.** Opdivo is a medicine that may treat certain cancers by working with your immune system. Opdivo can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended, and may be more common when Opdivo is used in combination with other treatments. Call or see your healthcare provider right away if you develop any new or worsening symptoms, including:

- Lung problems
  - new or worsening cough
  - shortness of breath
  - chest pain.
- Intestinal problems
  - diarrhea (loose stools) or more bowel movements than usual
  - stools that are black, tarry, sticky, or have blood or mucus
  - severe stomach-area (abdomen) pain or tenderness.
- Liver problems
  - yellowing of your skin or the whites of your eyes
  - dark urine (tea colored)
  - severe nausea or vomiting
  - bleeding or bruising more easily than normal
  - pain on the right side of your stomach area (abdomen).
- Hormone gland problems
  - headaches that will not go away or unusual headaches
  - urinating more often than usual
  - hair loss
  - eye sensitivity to light
  - eye problems
  - rapid heartbeat
  - increased sweating
  - extreme tiredness
  - weight gain or weight loss
  - feeling cold

- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased
- sex drive, irritability, or forgetfulness
- feeling more hungry or thirsty than usual.
- Kidney problems
  - decrease in your amount of urine
  - swelling in your ankles
  - blood in your urine
  - loss of appetite.
- Skin problems
  - rash
  - itching
  - skin blistering or peeling
  - painful sores or ulcers in your mouth or in your nose, throat, or genital area
  - fever or flu-like symptoms
  - swollen lymph nodes.

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with nivolumab. Call or see your healthcare provider right away for new or worsening symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising.

**Rejection of a transplanted organ or tissue.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ or tissue transplant that you have had.

Complications, including **graft-versus-host-disease** (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Opdivo. Your healthcare provider will monitor you for these complications.

Opdivo can cause severe **infusion-related reactions**. Tell your healthcare provider right away if you experience chest tightness, wheezing, shortness of breath, facial flushing, itching, hives, swelling, or any other allergic reaction.

Get emergency medical help if you have **signs of an allergic reaction** to Opdivo (hives, difficulty breathing, swelling in your face or throat) or a severe skin reaction (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with Opdivo. Your healthcare provider may treat you with corticosteroids or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with Opdivo if you have severe side effects.

Your cancer treatments may be delayed or permanently discontinued if you have certain side effects.

Opdivo may cause **harm to an unborn baby**. Females who can get pregnant should use an adequate form of contraception while being treated with Opdivo.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Opdivo side effects](#) (more detail)

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## Before taking this medicine

To make sure Opdivo is safe for you, tell your doctor if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have liver disease
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are similar to Opdivo
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

## Pregnancy

Opdivo may harm an unborn baby. You may need to have a negative pregnancy test before starting this treatment. Use effective birth control to prevent pregnancy while receiving Opdivo and for at least 5 months after your last dose. Tell your doctor right away if you become pregnant.

## Breastfeeding

It is not known if Opdivo passes into your breast milk. Do not breastfeed while using this medicine, and for at least 5 months after your last dose.

 [Opdivo pregnancy and breastfeeding warnings](#) (more detail)

## How is Opdivo administered?

Opdivo is given as an infusion into a vein (IV infusion) by a healthcare provider. This medicine must be given slowly over 30 minutes.

- Opdivo is usually given **once every 2 to 4 weeks**. Your other cancer medicines may be given on different schedules. Your doctor will determine how long to treat you with all medicines.
- The dosage of Opdivo depends on the cancer being treated and the patient's age (see the [Opdivo Prescribing Information](#) for complete Opdivo dosing information).
- You will need frequent medical tests to help your doctor determine if it is safe for you to keep receiving Opdivo.
- Opdivo can cause side effects in many different parts of your body. You may be given medication to prevent certain side effects, and your cancer treatments may be delayed if you need treatment for a side effect.

 [Detailed Opdivo dosage information](#)

## What happens if I miss a dose?



Call your doctor for instructions if you miss a chemotherapy appointment.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while receiving Opdivo?

Follow your doctor's instructions about restricting food, beverages, or activity.

## What other drugs will affect Opdivo?

Other drugs may interact with Opdivo, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Should not be given to patients with multiple myeloma who also take thalidomide medication in combination with dexamethasone unless they are part of a controlled clinical trial.

 [Opdivo drug interactions](#) (more detail)

## Does Opdivo interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

Opdivo

+

Enter a drug name

Add

## Storage

Your healthcare provider will store Opdivo refrigerated at 2°C to 8°C (36°F to 46°F) and protect it from light by storing it in the original package until the time of use.

Opdivo should not be frozen or shaken.

## Opdivo ingredients

**Active ingredient:** nivolumab

**Inactive ingredients:** mannitol, pentetic acid, polysorbate 80, sodium chloride, sodium citrate dihydrate, and Water for Injection. May contain hydrochloric acid and/or sodium hydroxide.

Available as a single-dose vial for intravenous infusion in the following strengths:

- 40 mg/4 mL (10 mg/mL)

- 100 mg/10 mL (10 mg/mL)
- 120 mg/12 mL (10 mg/mL)
- 240 mg/24 mL (10 mg/mL).

## Who makes Opdivo?

Opdivo (nivolumab) is made by Bristol Myers Squibb (BMS), headquartered in New York City.

## Opdivo Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

## Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Opdivo.

### Opdivo (nivolumab) - Bristol-Myers Squibb Company



Formulation type	Strength
Single-Dose Vial	100 mg/10 mL (10 mg/mL)
Single-Dose Vial	120 mg/12 mL (10 mg/mL)
Single-Dose Vial	240 mg/24 mL (10 mg/mL)
Single-Dose Vial	40 mg/4 mL (10 mg/mL)

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#### References

1. [Opdivo Package Insert](#)
2. [Opdivo Prescribing Information](#)

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- [Nivolumab \(AHFS Monograph\)](#)

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- [Esophageal Carcinoma](#)
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## Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

### DRUG STATUS

#### Availability

**Rx** Prescription only

#### [Pregnancy & Lactation](#)

 Risk data available

#### CSA Schedule\*

**N/A** Not a controlled drug

#### Approval History

**10 years** FDA approved 2014



## User Reviews & Ratings

5.8 / 10

[93 Reviews](#)

## Related News

[FDA Approves Opdivo \(nivolumab\) + Yervoy \(ipilimumab\) as a First-Line Treatment for Unresectable or Metastatic Hepatocellular Carcinoma](#)

[FDA Approves Opdivo \(nivolumab\) + Yervoy \(ipilimumab\) as a Treatment for Patients with Previously Untreated Microsatellite Instability-High or Mismatch Repair Deficient Unresectable or Metastatic Colorectal Cancer](#)

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