

Imfinzi

Pronunciation: *im-FIN-zee*

Generic name: durvalumab

Dosage form: injection (500 mg/10 mL, 120 mg/2.4 mL)

Drug class: Anti-PD-1 and PD-L1 monoclonal antibodies (immune checkpoint inhibitors)

Medically reviewed by Melisa Puckey, BPharm. Last updated on Dec 9, 2024.

What is Imfinzi?

Imfinzi (durvalumab) is an immunotherapy used to treat cancer, including certain non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), bile duct and gallbladder cancer, hepatocellular carcinoma, and endometrial cancer. Imfinzi may help increase overall survival, lower the chance of cancer spreading, and help shrink tumors, depending on the type of cancer. Imfinzi works by helping the immune system find, recognize, and fight cancer cells.

Imfinzi is given as an infusion into a vein every 2, 3, or 4 weeks, depending on your condition. Other medicines may be part of your treatment plan, depending on your cancer type.

Imfinzi FDA approval was granted on May 1, 2017, for the company AstraZeneca, originally for Advanced Bladder Cancer, but FDA approval has since be extended for use in more cancer types.

How does Imfinzi work?

Imfinzi works by binding and blocking the PD-L1 protein on the outside of cancer cells, which means your immune system can then find and attack the cancer cells to help slow cancer spreading and increase survival. Imfinzi's class of medicines is called checkpoint inhibitors.

Imfinzi mechanism of action (MOA) is as a programmed death-ligand 1 (PD-L1) blocking antibody. It binds and blocks PD-L1, so there is no interaction with PD-1 and CD80. This means that the immune response is now activated to work against the cancer cells.

Imfinzi can be used for cancers that have a protein called PD-L1 on the outside of the cancer cell. The PD-L1 protein helps the cancer cells hide it from the immune system so cancer cells can survive and multiply. When Imfinzi blocks PD-L1 it means the immune system is able to find cancers and destroy them.

What is Imfinzi used for?

Imfinzi indications are non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), biliary tract cancer, hepatocellular carcinoma, and endometrial cancer in specific patients. Imfinzi is a

prescription medicine that is FDA-approved to treat adults with:

Non-small cell lung cancer (NSCLC)

- Non-small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements who have with resectable (tumors ≥ 4 cm and/or node positive). To be used in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery.
- Unresectable Stage III NSCLC in patients whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. Imfinzi is to be used as a single agent.
- Metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations. Imfinzi, Imjudo (tremelimumab-actl) and platinum-based chemotherapy are to be used in combination for the treatment regime.

Small cell lung cancer (SCLC)

- in combination with the chemotherapy medicines etoposide and carboplatin or cisplatin when cancer has spread within your lungs or to other parts of the body
- as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).

Biliary tract cancer (including cancer of the bile ducts and gallbladder cancer) in combination with the chemotherapy medicines gemcitabine and cisplatin when cancer has spread to nearby tissues or other parts of the body

Hepatocellular carcinoma (unresectable) Imfinzi, Imjudo (tremelimumab-actl) are used in combination.

Endometrial cancer that has spread (advanced) or come back (recurrent) and tests show the tumor is mismatch repair deficient (dMMR), Imfinzi is used with carboplatin plus paclitaxel followed by single-agent Imfinzi.

Imfinzi side effects

Common Imfinzi side effects

Common Imfinzi side effects include shortness of breath (dyspnea), cough, rash, tiredness (fatigue), cold symptoms (respiratory tract infections) inflammation of the lungs (pneumonitis) when used as a single agent for Stage III NSCLC.

When used with other cancer treatments, common Imfinzi side effects may include nausea, constipation, decreased appetite, feeling weak or tired, bone or muscle pain, cough, feeling short of breath, cold symptoms such as stuffy nose, sneezing, sore throat, abdominal pain, fever, itchy skin, rash, painful urination, hair loss, vomiting, nerve inflammation (causing symptoms such as numbness, weakness, tingling, or burning), changes blood tests including decreased magnesium, increased ALT, and increased AST. Side effects profiles are dependent on the specific combination of therapies.

Immune-mediated hypothyroidism was reported in 14% of people receiving Imfinzi in combination with carboplatin and paclitaxel. Events resolved in some patients, but all required endocrine therapy.

Serious Imfinzi side effects

Imfinzi may cause serious side effects including severe allergic reactions. Get emergency medical help if you have signs of an allergic reaction to this medicine: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Some side effects may occur during the Imfinzi injection. Tell your caregiver right away if you feel light-headed or itchy or if you have a fever, chills, neck or back pain, trouble breathing, or flushing (warmth, redness, or tingly feeling).

This medicine causes your immune system to attack tumor cells, but it could also attack healthy organs and tissues in your body. This could lead to serious or life-threatening side effects on your lungs, liver, pancreas, kidneys, intestines, thyroid, or adrenal glands.

Call your doctor at once if you have:

- chest pain, new or worsening cough, feeling short of breath;
- severe stomach pain, diarrhea, bloody or tarry stools;
- new or worsening skin rash, itching, or blistering;
- fever, flu-like symptoms;
- pain or burning when you urinate;
- problems in other organs - mood or behavior changes, neck stiffness, confusion, eye pain or redness, vision problems;
- liver problems - loss of appetite, upper stomach pain, drowsiness, easy bruising or bleeding, dark urine, jaundice (yellowing of the skin or eyes);
- kidney problems - little or no urination, red or pink urine, swelling in your feet or ankles;
- transplant rejection - rash with blisters and peeling, watery diarrhea, stomach pain, vomiting, loss of appetite, fever, bruising or bleeding, jaundice, pain or swelling near your transplanted organ; or
- signs of a hormonal disorder - unusual headaches, feeling light-headed or very tired, hoarse or deepened voice, increased hunger or thirst, increased urination, constipation, vomiting, hair loss,

feeling cold, weight gain, or weight loss.

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

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.

 [Imfinzi side effects \(more detail\)](#)

Related/similar drugs

		FEATURES
Opdivo Opdivo is used to treat many different types of cancer such as melanoma, non-small cell lung ... Reviews & ratings 5.6 / 10 93 Reviews	Keytruda Keytruda is used to treat multiple types of cancer such as melanoma, non-small cell lung cancer ... Reviews & ratings 4.8 / 10 248 Reviews	Rybre Rybreva is used to treat non-small cell lung cancer ... Review 4 Review

Warnings

Imfinzi works by causing your immune system to attack tumor cells but it may also cause your immune system to attack healthy organs and tissues in your body. This could lead to serious or life-threatening side effects on your lungs, liver, pancreas, kidneys, intestines, thyroid, pituitary, or adrenal glands.

Call your doctor at once if you have new or unusual symptoms, such as: tiredness, mood changes, headaches, vision problems, muscle weakness, stomach problems, weight changes, skin rash, hair loss, bleeding or bruising, yellowing of your skin or eyes, increased or decreased urination, dark urine, bloody or tarry stools, worsening cough, chest pain, or trouble breathing.

Infusion-Related Reactions. Your infusion may be slowed, interrupted or permanently discontinued if you have an infusion-related reaction, depending on the severity of the reaction.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT). Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.

Embryo-Fetal Toxicity: This medicine can cause fetal harm. Females of reproductive potential should be advised of the potential risk to a fetus and should use effective contraception.

Before taking this medicine

You should not use this infusion if you are allergic to the active ingredient, durvalumab, or any of the inactive ingredients.

To make sure this medicine is safe for you, tell your doctor if you have an active infection or if you have ever had:

- an organ transplant or a stem cell transplant (recent or planned);
- lung disease or breathing problems;
- liver disease;
- radiation treatment of your chest area;
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome, or
- an autoimmune disorder such as lupus, ulcerative colitis, or Crohn's disease.

Pregnancy

Imfinzi may harm an unborn baby. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 3 months after your last dose. Tell your doctor if you become pregnant.

Breastfeeding

Do not breastfeed while using medicine, and for at least 3 months after your last dose.

 Imfinzi pregnancy and breastfeeding warnings (more detail)

How is Imfinzi given?

Imfinzi is given as an infusion into a vein, usually once every 2, 3 or 4 weeks. A healthcare provider will give you this injection.

This medicine must be given slowly, and the infusion can take about 1 hour to complete.

Imfinzi Dosing information

Usual Adult Dose for Small Cell Lung Cancer:

30 kg or less:

20 mg/kg IV in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 10 mg/kg every 4 weeks as a single agent until disease progression, unacceptable toxicity

NOTE: When this drug is given in combination with chemotherapy, administer this drug prior to chemotherapy on the same day; refer to the Prescribing Information for etoposide and carboplatin or cisplatin for dosing information.

Greater than 30 kg:

1500 mg IV in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent until disease progression or unacceptable toxicity

NOTE: When this drug is given in combination with chemotherapy, administer this drug prior to chemotherapy on the same day; refer to the Prescribing Information for etoposide and carboplatin or cisplatin for dosing information.

Use: First-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and either carboplatin or cisplatin.

Usual Adult Dose for Biliary Tract Cancer:**30 kg or less:**

20 mg/kg IV in combination with chemotherapy every 3 weeks (21 days) for up to 8 cycles, followed by 20 mg/kg every 4 weeks as a single agent until disease progression or until unacceptable toxicity

NOTE: When this drug is given in combination with chemotherapy, administer this drug prior to chemotherapy on the same day; refer to the Prescribing Information for gemcitabine and cisplatin for dosing information.

Greater than 30 kg:

1500 mg IV in combination with chemotherapy every 3 weeks (21 days) for up to 8 cycles, followed by 1500 mg every 4 weeks as a single agent until disease progression or until unacceptable toxicity

NOTE: When this drug is given in combination with chemotherapy, administer this drug prior to chemotherapy on the same day; refer to the Prescribing Information for gemcitabine and cisplatin for dosing information.

Use: Locally advanced or metastatic biliary tract cancer (BTC) in combination with gemcitabine and cisplatin.

Usual Adult Dose for Unresectable Hepatocellular Carcinoma:**Less than 30 kg:**

20 mg/kg in combination with tremelimumab-actl 4 mg/kg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks.

Greater than or equal to 30 kg:

1,500 mg in combination with tremelimumab-actl 300 mg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks.

Use: The treatment of adult patients with unresectable hepatocellular carcinoma in combination with tremelimumab-actl.

Usual Adult Dose for dMMR endometrial cancer

30 kg or less:

15 mg/kg in combination with carboplatin and paclitaxel* every 3 weeks (21 days) for 6 cycles, followed by Imfinzi 20 mg/kg every 4 weeks as a single agent Until disease progression or unacceptable toxicity.

Greater than 30 kg:

1,120 mg in combination with carboplatin and paclitaxel* every 3 weeks (21 days) for 6 cycles, followed by Imfinzi 1,500 mg every 4 weeks as a single agent.


Use: to treat endometrial cancer that has spread (advanced) or come back (recurrent) and tests show the tumor is mismatch repair deficient (dMMR), Imfinzi is used with carboplatin plus paclitaxel followed by single-agent Imfinzi.

Usual Adult Dose for Non-Small Cell Lung Cancer:

For detailed dose information for non-Small Cell Lung Cancer, see Detailed Imfinzi Dosage.

Imfinzi is available as

- 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.
- 120 mg/2.4 mL (50 mg/mL) solution in a single-dose vial.

 Detailed Imfinzi dosage information

Imfinzi J code

Imfinzi J code is J9173, Injection durvalumab, 10 mg.

J codes are used for medicines that are not taken orally and include injections, inhalations chemotherapies. J codes are important, accurate, and consistent coding for billing and reimbursement purposes. They are part of the Healthcare Common Procedure Coding System (HCPCS). Your physician will need an Imfinzi J-code when filling out forms for your treatment.

J9173 Injection durvalumab, 10 mg

Vials size and NDC codes

- 500 mg/10 ml 50 units NDC 0310-4611-50
- 120 mg/24 ml 12 units NDC 0310-4500-12

What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your Imfinzi injection.

What happens if I overdose?


Since this medicine is given by a healthcare professional in a medical setting, an overdose is unlikely to occur.

What should I avoid while receiving Imfinzi?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

What other drugs will affect Imfinzi?

Other drugs may interact with durvalumab, 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.

 [Imfinzi drug interactions \(more detail\)](#)

Imfinzi Package Insert

Review the Imfinzi Package Insert for more detailed information about this medicine. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

Imfinzi Package Insert is sometimes called Imfinzi Prescribing Information (PI) or Imfinzi FDA label.

Imfinzi Copay Card or Copay assistance

Imfinzi Copay Card or Copay assistance may help you pay a set amount of out-of-pocket costs, if you are covered by commercial insurance and your insurance does not cover the full cost of their prescription. For links to Imfinzi Copay Card or Copay assistance click here [Imfinzi Prices, Coupons, Copay Cards](#).

Ingredients

Active ingredient: durvalumab

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, α,α -trehalose dihydrate, polysorbate 80, Water for Injection, USP.

Imfinzi manufacturer

Imfinzi manufacturer is AstraZeneca UK Limited, 1 Francis Crick Ave. Cambridge, England CB2 0AA

Imfinzi is Manufactured for AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

Imfinzi 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 Imfinzi.

Imfinzi (durvalumab) - AstraZeneca UK Ltd



Formulation type	Strength
Single-Dose Vial	120 mg/2.4 mL (50 mg/mL)
Single-Dose Vial	500 mg/10 mL (50 mg/mL)

Frequently asked questions

- What type of drug is Imfinzi?

References

1. Imfinzi Product Label
2. National Cancer Institute at the National Institutes of Health: Immune Checkpoint Inhibitors

Further information

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