

Package leaflet: Information for the patient

IMFINZI® 50 mg/mL concentrate for solution for infusion durvalumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IMFINZI is and what it is used for
2. What you need to know before you are given IMFINZI
3. How you are given IMFINZI
4. Possible side effects
5. How to store IMFINZI
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1. What IMFINZI is and what it is used for

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC) in adults. It is used when your NSCLC:

- has spread within your lung and cannot be removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

IMFINZI is used to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC) in adults. It is used when your SCLC:

- has spread within your lungs (or to other parts of the body) and
- has not previously been treated.

IMFINZI contains the active substance durvalumab which is a monoclonal antibody, a type of protein designed to recognise a specific target substance in the body. IMFINZI works by helping your immune system fight your cancer.

If you have any questions about how IMFINZI works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

IMFINZI will be given in combination with chemotherapy for SCLC. It is important that you also read the package leaflets for the specific chemotherapy you may be receiving. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you are given IMFINZI

You should not be given IMFINZI

- if you are allergic to durvalumab or any of the other ingredients of this medicine (listed in section 6 “Contents of the pack and other information”). Talk to your doctor if you are not sure.

Warnings and precautions

Talk to your doctor before you are given IMFINZI if:

- you have an autoimmune disease (an illness where the body's immune system attacks its own cells);
- you have had an organ transplant;
- you have lung problems or breathing problems;
- you have liver problems.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given IMFINZI.

When you are given IMFINZI, you can have some serious side effects.

If you have any of the following, call or see your doctor straight away. Your doctor may give you other medicines that prevent more severe complications and to help reduce your symptoms. Your doctor may delay the next dose of IMFINZI or stop your treatment with IMFINZI, if you have:

- **inflammation of the lungs:** symptoms may include new or worsening cough, shortness of breath or chest pain;
- **inflammation of the liver:** symptoms may include nausea or vomiting, feeling less hungry, pain on the right side of your stomach, yellowing of skin or whites of eyes, drowsiness, dark urine or bleeding or bruising more easily than normal;
- **inflammation of the intestines:** symptoms may include diarrhoea or more bowel movements than usual, or stools that are black, tarry or sticky with blood or mucus, severe stomach pain or tenderness;
- **inflammation of glands:** (especially the thyroid, adrenal, pituitary and pancreas): symptoms may include fast heart rate, extreme tiredness, weight gain or weight loss, dizziness or fainting, hair loss, feeling cold, constipation, headaches that will not go away or unusual headaches;
- **type 1 diabetes:** symptoms may include high blood sugar, feeling more hungry or thirsty than usual, passing urine more often than usual, fast and deep breathing, confusion, or a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat;
- **inflammation of the kidneys:** symptoms may include decrease in the amount of urine you pass;
- **inflammation of the skin:** symptoms may include rash, itching, skin blistering or ulcers in the mouth or on other moist surfaces;
- **inflammation of the heart muscle:** symptoms may include chest pain, shortness of breath or irregular heartbeat;
- **inflammation or problems of the muscles:** symptoms may include muscle pain, or weakness or rapid fatigue of the muscles;
- **infusion-related reactions:** symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing dizziness or fever;
- **inflammation of the brain (encephalitis) or inflammation of the membrane around the spinal cord and brain (meningitis):** symptoms may include seizures, neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness;
- **inflammation of the nerves:** symptoms may include pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome);
- **low number of platelets:** symptoms may include bleeding (nose or gum bleeding) and/or bruising.

If you have any of the symptoms listed above, call or see your doctor straight away.

Children and adolescents

IMFINZI should not be used in children and adolescents below 18 years of age.

Other medicines and IMFINZI

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription.

Pregnancy

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are a woman who could become pregnant you must use effective birth control while you are being treated with IMFINZI and for at least 3 months after your last dose.

Breast-feeding

- Tell your doctor if you are breast-feeding.
- Ask your doctor if you can breast-feed during or after treatment with IMFINZI.
- It is not known if IMFINZI passes into human breast milk.

Driving and using machines

IMFINZI is not likely to affect you being able to drive and use machines.

However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving or operating machines.

3. How you are given IMFINZI

IMFINZI will be given to you in a hospital or clinic under the supervision of an experienced doctor.

- The recommended dose of IMFINZI is 10 mg per kg of your body weight every 2 weeks or 1500 mg every 3 or 4 weeks.
- Your doctor will give you IMFINZI through an infusion (drip) into your vein for about 1 hour.
- Your doctor will decide how many treatments you need.

If you miss an appointment to get IMFINZI

- Call your doctor straight away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

If you have any further questions about your treatment, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you get IMFINZI, you can have some serious side effects (see section 2).

Talk to your doctor straight away if you get any of the following side effects, that have been reported in clinical trials with patients receiving IMFINZI alone and includes the serious side effects listed in section 2:

Very common (may affect more than 1 in 10 people)

- infections of the upper respiratory tract
- underactive thyroid gland that can cause tiredness or weight gain
- cough
- diarrhoea
- stomach pain
- skin rash or itchiness
- fever

Common (may affect up to 1 in 10 people)

- serious lung infections (pneumonia)

- fungal infection in the mouth
- tooth and mouth soft tissue infections
- flu-like illness
- overactive thyroid gland that can cause fast heart rate or weight loss
- inflammation of the lungs (pneumonitis)
- hoarse voice (dysphonia)
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- night sweats
- muscle pain (myalgia)
- abnormal kidney function tests (blood creatinine increased)
- painful urination
- swelling of the legs (oedema peripheral)
- reaction to the infusion of the medicine that can cause fever or flushing

Uncommon (may affect up to 1 in 100 people)

- inflammation of thyroid gland
- decreased secretion of hormones produced by the adrenal glands that can cause tiredness
- scarring of lung tissue
- inflammation of the liver that can cause nausea or feeling less hungry
- blistering of the skin
- inflammation of the gut or intestine (colitis)
- inflammation of the muscle
- inflammation of the kidneys (nephritis) that can decrease the amount of your urine

Rare (may affect up to 1 in 1000 people)

- a condition leading to high blood sugar levels (type 1 diabetes mellitus)
- underactive function of pituitary gland (hypopituitarism including diabetes insipidus) that can cause tiredness, an increase in the amount of your urine
- inflammation of the heart
- a condition in which the muscles become weak and there is a rapid fatigue of the muscles (myasthenia gravis)
- inflammation of the membrane around the spinal cord and brain (meningitis)
- low number of platelets caused by an immune reaction (immune thrombocytopenia)
- Inflammation of the bladder. Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen.

The following side effects have been reported in clinical trials in patients taking IMFINZI in combination with chemotherapy:

Very common (may affect more than 1 in 10 people)

- low number of white blood cells
- low number of red blood cells
- low number of platelets
- nausea; vomiting; constipation
- hair loss
- feeling less hungry
- feeling tired or weak
- cough

Common (may affect up to 1 in 10 people)

- diarrhoea
- fever
- low number of white blood cells with signs of fever
- skin rash or itchiness
- underactive thyroid gland; overactive thyroid gland; inflammation of thyroid gland

- serious lung infections (pneumonia)
- tooth and mouth soft tissue infections
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- swelling of legs (oedema peripheral)
- stomach pain
- inflammation of the mouth or lips
- muscle pain (myalgia)
- inflammation of the lungs (pneumonitis)
- infection of the upper respiratory tract
- low number of red blood cells, white blood cells, and platelets (Pancytopenia)
- decreased secretion of hormones produced by the adrenal glands that can cause tiredness
- inflammation of the liver that can cause nausea or feeling less hungry
- abnormal kidney function tests (blood creatinine increased)
- painful urination
- reaction to the infusion of the medicine that can cause fever or flushing

Uncommon (may affect up to 1 in 100 people)

- fungal infection in the mouth
- flu-like illness
- type 1 diabetes mellitus
- hoarse voice (dysphonia)
- scarring of lung tissue
- inflammation of the gut or intestine (colitis)
- night sweats

Talk to your doctor straight away if you get any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store IMFINZI

IMFINZI will be given to you in a hospital or clinic and the healthcare professional will be responsible for its storage. The storage details are as follows:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP.

The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Store in the original package in order to protect from light.

Do not use if this medicine is cloudy, discoloured or contains visible particles.

Do not store any unused portion of the infusion solution for re-use. Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What IMFINZI contains

The active substance is durvalumab.

Each mL of concentrate for solution for infusion contains 50 mg of durvalumab.

Each vial contains either 500 mg of durvalumab in 10 mL of concentrate or 120 mg of durvalumab in 2.4 mL of concentrate.

The other ingredients are: histidine, histidine hydrochloride monohydrate, trehalose dihydrate, polysorbate 80, water for injections.

What IMFINZI looks like and contents of the pack

IMFINZI concentrate for solution for infusion is a sterile, preservative-free, clear to opalescent, colourless to slightly yellow solution, free from visible particles.

It is available in packs containing either 1 glass vial of 2.4 mL of concentrate or 1 glass vial of 10 mL of concentrate.

Marketing Authorisation Holder

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Manufacturer

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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	Reference number
Imfinzi 50mg/ml solution for infusion	17901/0327