

## 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
6. Contents of the pack and other information

#### 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 in combination with chemotherapy 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 in combination with chemotherapy is used in adults to treat a type of cancer of the bile ducts (cholangiocarcinoma) and gallbladder that are collectively referred to as biliary tract cancers (BTC). It is used when your BTC:

- has spread within your bile ducts and gallbladder (or to other parts of the body).

IMFINZI in combination with tremelimumab is used to treat a type of liver cancer called advanced or unresectable hepatocellular carcinoma (HCC) in adults. It is used when your HCC:

- cannot be removed by surgery (unresectable), and
- may have spread within your liver or to other parts of the body.

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.

When IMFINZI is given in combination with other anti-cancer medicines, it is important that you also read the package leaflet for these other medicines. 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, hole in the bowel;
- **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, abdominal pain, nausea and vomiting;
- **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;
- **inflammation of the spinal cord** (transverse myelitis): symptoms may include pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation;

- **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);
- **inflammation of the joints:** signs and symptoms include joint pain, swelling, and/or stiffness (immune-mediated arthritis);
- **inflammation of the eye:** signs and symptoms include eye redness, eye pain, light sensitivity, and/or changes in vision (uveitis);
- **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.

IMFINZI acts on your immune system. It may cause inflammation in parts of your body. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild.

### **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.
- Depending on your type of cancer, IMFINZI may be given in combination with other anti-cancer medicines.

- When IMFINZI is given in combination with chemotherapy for your lung cancer, you will first be given IMFINZI followed by chemotherapy.
- When IMFINZI is given in combination with tremelimumab for your liver cancer, you will first be given tremelimumab followed by IMFINZI.
- Please refer to the package leaflet of the other anti-cancer medicines in order to understand the use of these other medicines. If you have questions about these medicines, ask your doctor.

#### **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:

##### **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
- joint pain (arthralgia)

##### **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 (dysuria)
- swelling of the legs (oedema peripheral)
- reaction to the infusion of the medicine that can cause fever or flushing
- blistering of the skin

##### **Uncommon (may affect up to 1 in 100 people)**

- inflammation of thyroid gland (thyroiditis)
- 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 (hepatitis)
- inflammation of the gut or intestine (colitis)
- inflammation of the muscle (myositis)
- inflammation of the kidneys (nephritis) that can decrease the amount of your urine
- inflammation of the pancreas (pancreatitis)
- red, itchy, dry, scaly patches of thickened skin (psoriasis)

**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 (myocarditis)
- 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 (cystitis). Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen
- inflammation of the eye (uveitis)
- inflammation of the joints (immune-mediated arthritis)

**Other side effects that have been reported with frequency not known (cannot be estimated from the available data)**

- inflammation of the nerves: (Guillain-Barré syndrome)
- transverse myelitis

The following side effects have been reported in clinical trials in patients taking IMFINZI in combination with chemotherapy (the frequency and severity of side effects may vary depending on chemotherapeutic agents received):

**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, stomach pain, diarrhoea
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- hair loss
- rash, red raised rash, dry or itchy skin; inflammation of the skin
- fever
- feeling less hungry
- feeling tired or weak
- cough

**Common (may affect up to 1 in 10 people)**

- low number of white blood cells with signs of fever
- underactive thyroid gland; overactive thyroid gland; inflammation of thyroid gland
- lack of energy; general feeling of discomfort or illness
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs (peripheral neuropathy)
- shortness of breath
- serious lung infections (pneumonia)
- tooth and mouth soft tissue infections
- swelling (oedema)
- swelling of legs (oedema peripheral)
- inflammation of the mouth or lips

- muscle pain (myalgia)
- inflammation of the lungs (pneumonitis)
- blood clot in the lung (pulmonary embolism)
- 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 (hepatitis)
- abnormal kidney function tests (blood creatinine increased)
- painful urination (dysuria)
- reaction to the infusion of the medicine that can cause fever or flushing
- fungal infection in the mouth
- joint pain (arthralgia)
- blistering of the skin

**Uncommon (may affect up to 1 in 100 people)**

- flu-like illness
- type 1 diabetes mellitus
- hoarse voice (dysphonia)
- scarring of lung tissue
- inflammation of the gut or intestine (colitis)
- night sweats
- red, itchy, dry, scaly patches of thickened skin (psoriasis)
- inflammation of the pancreas (pancreatitis)
- inflammation of the joints (immune-mediated arthritis)

**Rare (may affect up to 1 in 1 000 people)**

- inflammation of the eye (uveitis)

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

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

- underactive thyroid gland that can cause tiredness or weight gain
- cough
- diarrhoea
- stomach pain
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- skin rash
- itchiness
- fever
- swelling of legs (oedema peripheral)

**Common (may affect up to 1 in 10 people)**

- infection of the upper respiratory tract
- lung infection (pneumonia)
- flu-like illness
- tooth and mouth soft tissue infections
- overactive thyroid gland that can cause fast heart rate or weight loss
- inflammation of the thyroid gland (thyroiditis)
- decreased secretion of hormones produced by the adrenal glands that can cause tiredness
- inflammation of the lungs (pneumonitis)
- abnormal pancreas function tests
- inflammation of the gut or intestine (colitis)
- inflammation of the pancreas (pancreatitis)

- inflammation of the liver (hepatitis)
- inflammation of the skin
- night sweats
- muscle pain (myalgia)
- abnormal kidney function test (blood creatinine increased)
- painful urination (dysuria)
- 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
- underactive pituitary gland; inflammation of pituitary gland
- 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)
- inflammation of the heart (myocarditis)
- hoarse voice (dysphonia)
- scarring of lung tissue
- blistering of the skin
- inflammation of the muscles (myositis)
- inflammation of the muscles and vessels
- inflammation of the kidneys (nephritis) that can decrease the amount of your urine
- inflammation of the joints (immune-mediated arthritis)

**Rare (may affect up to 1 in 1,000 people)**

- inflammation of the eye (uveitis)

**Other side effects that have been reported with frequency not known (cannot be estimated from the available data)**

- low number of platelets with signs of excessive bleeding and bruising (immune thrombocytopenia)
- diabetes insipidus
- type 1 diabetes mellitus
- inflammation of the nerves: (Guillain-Barré syndrome)
- inflammation of the brain (encephalitis)
- hole in the bowel (intestinal perforation)
- inflammation of the bladder (cystitis). Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen.

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](http://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**

AstraZeneca UK Limited,  
1 Francis Crick Avenue,  
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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:

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