PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IMFINZI 120 mg concentrate for solution for infusion

IMFINZI 500 mg concentrate for solution for infusion

Durvalumab

Sugar-free

Read all of this leaflet carefully before you are given IMFINZI

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or~~ pharmacist, nurse or other health care provider.
- IMFINZI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What IMFINZI is and what it is used for
2. What you need to know before you use IMFINZI
3. How to use 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

The active substance is durvalumab.

IMFINZI is used to treat:

1. Urothelial Carcinoma

IMFINZI is used to treat a type of bladder cancer called muscle invasive bladder cancer (MIBC) which is when your bladder cancer has spread into the muscle layer of the bladder but not to other parts of the body. It is used in combination with chemotherapy (neoadjuvant treatment) prior to the surgical removal of your bladder followed by IMFINZI alone after surgery (adjuvant treatment).

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2. Lung cancer

Non-Small Cell Lung cancer (NSCLC):

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when NSCLC has spread within the lung and cannot be removed by surgery and has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

IMFINZI in combination with tremelimumab and platinum-based chemotherapy is used for the first-line treatment of patients with a type of NSCLC that has spread within the lungs and/or other parts of the body and has shown no changes (mutations) in genes called EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase).

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It may be used in combination with chemotherapy prior to surgery (neoadjuvant treatment) and alone after surgery (adjuvant treatment) when your NSCLC has spread within your lung and is able to be removed by surgery .

Small Cell Lung Cancer (SCLC):

IMFINZI is used in together with chemotherapy to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC). It is used when SCLC has spread within the lungs (or to other parts of the body) and has not previously been treated.

IMFINZI is used to treat a type of lung cancer called limited-stage small cell lung cancer (LS-SCLC). It is used when your LS-SCLC:

- has not been removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

3. Liver cancer

IMFINZI in combination with tremelimumab is used to treat a type of liver cancer, called unresectable hepatocellular carcinoma (uHCC). It is used when uHCC cannot be removed by surgery (unresectable) and may have spread within the liver or to other parts of the body.

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4 Biliary tract cancer

IMFINZI is used to treat a type of cancer called biliary tract cancer (BTC), such as cancer of the bile ducts and gallbladder. It is used when BTC has spread within these regions (or to other parts of the body).

5. Gastric cancer (GC) or gastro-oesophageal junction adenocarcinoma (GEJC)

IMFINZI is used to treat a type of stomach cancer called gastric cancer (GC) or gastro-oesophageal junction adenocarcinoma (GEJC) that can be removed by surgery. It is used in combination with chemotherapy prior to and after surgery, followed by IMFINZI alone.

When IMFINZI is given in combination with other medicines, it is important that you also read the patient information leaflet for the specific anti-cancer medicines. If you have any questions about these medicines, ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE IMFINZI

You should not be given IMFINZI:

- if you are hypersensitive (allergic) to durvalumab or any of the other ingredients of IMFINZI listed in section 6.1.

Warnings and precautions

Take special care with IMFINZI

Tell your doctor or healthcare professional before being given the injection if you:

- have immune system problems such as Crohn's disease, ulcerative colitis or lupus.
- have had an organ transplant.
- have lung or breathing problems.
- have liver problems.
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 3 months after the last dose of IMFINZI.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI passes into your breast milk. Do not breastfeed during treatment and for at least 3 months after the last dose of IMFINZI.

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

If you have any of the following, tell your doctor immediately. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of IMFINZI or stop your treatment with IMFINZI:

- inflammation of the lungs: signs and symptoms may include new or worsening cough, shortness of breath or chest pain.
- inflammation of the liver: signs and symptoms may include nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, drowsiness, dark urine or bleeding or bruising more easily than normal.
- inflammation of the intestines: signs and symptoms may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucous severe stomach pain or tenderness.
- inflammation of hormone glands (especially the thyroid, adrenals, pituitary and pancreas): signs and symptoms may include headaches that will not go away or unusual headaches, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, changes to your voice, urinating more often than usual, nausea or vomiting, stomach area (abdomen) pain, changes in mood or behaviour, such as decreased sex drive, irritability or forgetfulness.
- inflammation of the kidneys: signs and symptoms may include changes in the amount or colour of your urine, swelling in your ankles or loss of appetite.
- inflammation of the skin or mouth: signs and symptoms may include rash, itching, skin blistering or ulcers in mouth or other mucous membranes.
- inflammation of the heart: signs and symptoms may include chest pain, shortness of breath or irregular heartbeat.
- inflammation of muscles: signs and symptoms may include severe muscle weakness, tiredness or pain, in one or more areas of your body.
- infusion related reactions: signs and symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing dizziness, fever, feeling like passing out, back or neck pain or facial

swelling.

- *Human Immunodeficiency Virus (HIV):* IMFINZI has not been studied in patients with HIV.

Children and adolescents

IMFINZI has not been studied in children or adolescents. Do not give this medicine to children or adolescents aged less than 18 years.

Other medicines and IMFINZI

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
If you are a woman who could become pregnant, you must use adequate birth control while you are being treated with IMFINZI and for at least 3 months after your last dose.
Do not breastfeed while taking IMFINZI and for at least 3 months after last dose.
It is not known if IMFINZI passes into your breast milk.

Driving and using machines:

IMFINZI is unlikely to affect the ability to drive and use machines.
However, if you experience adverse reactions affecting your ability to concentrate and react, you should use caution when driving or operating machinery.

3. HOW TO USE IMFINZI

Do not share medicines prescribed for you with any other person.

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.

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Your doctor will give you IMFINZI through an infusion (drip) into your vein (IV) for about 60 minutes. Your doctor will decide how many treatments you need.

When IMFINZI is given in combination with chemotherapy, you will first be given IMFINZI followed by chemotherapy.

When IMFINZI is given in combination with tremelimumab and chemotherapy for lung cancer, you will first be given tremelimumab followed by IMFINZI and then by chemotherapy.

If you miss an appointment to get IMFINZI

Call your doctor or healthcare professional right away to reschedule your appointment. It is very important that you do not miss a dose of IMFINZI.

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

4. POSSIBLE SIDE EFFECTS

IMFINZI can have side effects.

Not all side effects reported for IMFINZI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using IMFINZI, please consult your health_care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- inflammation of the lungs (pneumonitis)
- stomach pain
- fever
- lung infection (pneumonia)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- cough
- diarrhoea

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- stomach pain
- skin rash or itchiness
- fever
- swelling of the legs (peripheral oedema)
- upper respiratory tract infection

The following side effects have been reported less frequently:

- fungal infection in the mouth
- flu-like illness
- raised blood sugar levels (type 1 diabetes mellitus)
- hoarse voice (dysphonia)
- inflammation of the gut or intestine (colitis)
- night sweats

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PRODUCT.

5. HOW TO STORE IMFINZI

Store all medicines out of reach of children.

Store at 2 – 8 °C (in a refrigerator)

Do not freeze. Do not shake.

Store in the original package to protect from light.

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

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

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IMFINZI contains

IMFINZI 120 mg:

2,4 ml of concentrate in a 10 ml Type 1 glass vial with an elastomeric stopper and a gray flip-off aluminum seal contains 120 mg durvalumab. Pack size of 1 vial.

IMFINZI 500 mg:

10 ml of concentrate in a 10 ml Type 1 glass vial with an elastomeric stopper and a white flip-off aluminum seal contains 500 mg durvalumab. Pack size of 1 vial.

The other ingredients are L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate and polysorbate 80.

What IMFINZI looks like and contents of the pack -

The solution in the vial is sterile, preservative-free, clear to opalescent, colourless to slightly yellow and free from visible particles.

Holder of Certificate of Registration

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13 January 2026

REGISTRATION NUMBERS

IMFINZI 120 mg/2,4 ml: 54/30.1/0001

IMFINZI 500 mg/10 ml: 54/30.1/0002

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Access to the corresponding Professional Information

AstraZeneca Logo

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