

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using IMFINZI, speak to your doctor or pharmacist.

▼ IMFINZI is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using IMFINZI?

IMFINZI contains the active ingredient durvalumab. IMFINZI is used to treat several kind of cancers.

For more information, see Section [1. Why am I using IMFINZI?](#) in the full CMI.

2. What should I know before I use IMFINZI?

Do not use if you have ever had an allergic reaction to IMFINZI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use IMFINZI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMFINZI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use IMFINZI?

- IMFINZI will be given to you as a liquid infusion into your vein and your doctor will decide how many treatments you need.

More instructions can be found in Section [4. How do I use IMFINZI?](#) in the full CMI.

5. What should I know while using IMFINZI?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using IMFINZI.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not miss a dose of IMFINZI
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how IMFINZI affects you.

For more information, see Section [5. What should I know while using IMFINZI?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, IMFINZI can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

When you take IMFINZI, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring due to provisional approval of an extension of indication. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

IMFINZI®

Active ingredient(s): *durvalumab*

IMFINZI has **provisional approval** to treat a type of mesothelioma cancer called malignant pleural mesothelioma with epithelioid histology. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence in a larger group of patients is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMFINZI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IMFINZI.**

Where to find information in this leaflet:

- [1. Why am I using IMFINZI?](#)
- [2. What should I know before I use IMFINZI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use IMFINZI?](#)
- [5. What should I know while using IMFINZI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using IMFINZI?

IMFINZI contains the active ingredient durvalumab. IMFINZI is a monoclonal antibody, a type of protein. It is a type of immunotherapy and belongs to a group of medicines called immune checkpoint inhibitors. It works with your immune system to destroy cancer cells.

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It will be prescribed to you if:

- your cancer has spread within your lung and cannot be removed by surgery and;
- you have tried radiation and chemotherapy that contains platinum, and your cancer has shrunk or has not worsened.

IMFINZI in combination with chemotherapy is used to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC). It will be prescribed to you if:

- your cancer has spread within your lungs (or to other parts of the body) and
- you have not received previous treatment.

IMFINZI in combination with chemotherapy is also provisionally approved to treat a type of mesothelioma cancer called malignant pleural mesothelioma (MPM) with epithelioid histology. It will be prescribed to you if:

- your cancer has spread and cannot be removed by surgery and;
- you have not received previous treatment.

IMFINZI in combination with chemotherapy is used to treat a type of cancer called biliary tract cancer (BTC), such as cancer of the bile ducts (cholangiocarcinoma) and gallbladder. It will be prescribed to you if:

- your cancer has spread within these regions (or to other parts of the body).

IMFINZI in combination with tremelimumab is used to treat a type of liver cancer, called unresectable hepatocellular carcinoma (uHCC). It will be prescribed to you if:

- your cancer cannot be removed by surgery (unresectable) and;
- your cancer has spread within your liver (or to other parts of the body)

When IMFINZI is given in combination, it is important that you also read the Consumer Medicine Information (CMI) for the specific anti-cancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

Your doctor may have prescribed IMFINZI for another reason.

2. What should I know before I use IMFINZI?

Warnings

Do not use IMFINZI if:

- you are allergic to durvalumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use IMFINZI.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions (including immune system problems such as Crohn's disease, ulcerative colitis, or lupus; have had an organ transplant; have lung or breathing problems or have liver problems)
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

You should not be given IMFINZI if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not be given IMFINZI if you are breast-feeding.

It is not known if the active ingredient in IMFINZI passes into breast milk, but if it does, there is a possibility that your baby may be affected.

Do not breast-feed if you are being given IMFINZI and for at least 3 months after the last dose.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IMFINZI.

4. How do I use IMFINZI?

How much and when to take IMFINZI

- IMFINZI will be given to you as a liquid infusion into your vein (IV). An infusion takes about 1 hour and will normally be given every 2, 3 or 4 weeks. Depending on your type of cancer, IMFINZI may be given in combination with other anti-cancer medicines.
- Your doctor will decide how many treatments you need.

When IMFINZI is given in combination with chemotherapy for your lung cancer (NSCLC, ES-SCLC or MPM) and biliary tract (BTC), 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 CMI 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 be given IMFINZI

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

5. What should I know while using IMFINZI?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

Remind any doctor, dentist or pharmacist you visit that you are using IMFINZI.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IMFINZI affects you.

IMFINZI is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

- Store unopened vials under refrigeration at 2°C to 8°C in the original carton to protect from light.
- Do not freeze.
- Do not shake.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use IMFINZI or it is out of date, take it to any pharmacy for safe disposal.

Do not use IMFINZI after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

IMFINZI can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work and this can cause the side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Problems with your lungs:</p> <ul style="list-style-type: none">• lung inflammation that may include new or worsening cough, shortness of breath, chest pain• chronic Obstructive Pulmonary Disorder (COPD) which causes the narrowing of airways and makes it difficult to breathe.• lung infection (pneumonia or influenza) that may include coughing of phlegm, fever, chills and difficulty breathing. <p>Problems with your liver:</p> <ul style="list-style-type: none">• inflammation of the liver that 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. <p>Problems with your intestines:</p> <ul style="list-style-type: none">• inflammation of the intestines may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucous, severe stomach pain or tenderness.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Problems with of some of your hormone glands:</p> <ul style="list-style-type: none"> inflammation of your hormone glands 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, increased anxiety, irritability or forgetfulness, 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. <p>Problems with your kidney:</p> <ul style="list-style-type: none"> inflammation of your kidney that may include changes in the amount or colour of your urine, swelling in your ankles or loss of appetite. <ul style="list-style-type: none"> Problems with your urinary tract: infection that may include the need to urinate urgently and frequently, burning pain or sensation when urinating, bladder still feels full after urinating, pain above your pubic bone, blood in the urine. <p>Problems with your skin or mouth:</p> <ul style="list-style-type: none"> inflammation of the skin or mouth may include rash, itching, skin blistering or ulcers in the mouth or other mucous membranes. thrush in the mouth. <p>Problems with your nose and throat:</p> <ul style="list-style-type: none"> nose or throat infection (sinusitis or tonsillitis) <p>Problems with your heart:</p> <ul style="list-style-type: none"> inflammation of your heart may include chest pain, shortness of breath or irregular heartbeat. <p>Problems with your muscles:</p> <ul style="list-style-type: none"> inflammation of your muscles may include muscle weakness, tiredness and/or pain, and/or 	

Serious side effects	What to do
<p>rapid fatigue of the muscles, in one or more areas of your body.</p> <p>Low number of platelets:</p> <ul style="list-style-type: none"> May include bleeding (e.g. nose or gum bleeding) and/or bruising. <p>Infusion-related reactions:</p> <ul style="list-style-type: none"> 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. <p>Encephalitis or meningitis:</p> <ul style="list-style-type: none"> may include seizures, neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness. <p>Guillain-Barré syndrome:</p> <ul style="list-style-type: none"> may include pain, weakness, and paralysis in the extremities. <p>General body:</p> <ul style="list-style-type: none"> An inflammatory response that may include low or high body temperature, increased heart rate, increased breathing rate and/or abnormal white blood cell count <p>Problems with your immune system:</p> <ul style="list-style-type: none"> Immune system attacking your red blood cells - signs and symptoms may include unusual weakness and fatigue with increased heart rate and breathing difficulties, yellowing of the skin or whites of the eyes (jaundice), dark urine and/or an enlarged spleen <p>Inflammation of the spinal cord:</p> <ul style="list-style-type: none"> 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 	
<p>Problems with your eyes:</p> <ul style="list-style-type: none"> Inflammation of your eyes (uveitis) - signs and symptoms include eye redness, eye pain, light sensitivity, and/or changes in vision 	<p>Contact a medical eye specialist (ophthalmologist) straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
	notice these side effects as you may need urgent medical attention.

Most common side effects reported in clinical trials:

Most common side effects	What to do
<p>Reported in clinical trials with patients receiving IMFINZI alone:</p> <ul style="list-style-type: none"> cough diarrhoea stomach pain skin rash or itchiness fever swelling of the legs (oedema peripheral) upper respiratory tract infection underactive thyroid gland that can cause tiredness or weight gain <p>Reported in a clinical trial with patients receiving IMFINZI with etoposide and carboplatin or cisplatin:</p> <ul style="list-style-type: none"> nausea hair loss decreased appetite feeling tired or weak constipation vomiting cough <p>Reported in clinical trials with patients receiving IMFINZI with pemetrexed and cisplatin or carboplatin:</p> <ul style="list-style-type: none"> fatigue nausea constipation <p>Reported in clinical trials with patients receiving IMFINZI with gemcitabine and cisplatin:</p> <ul style="list-style-type: none"> low number of red blood cells (anaemia) low number of white blood cells (neutropenia and leukopenia) low number of platelets (thrombocytopenia) diarrhoea abdominal pain constipation nausea vomiting feeling tired or weak fever abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased) decrease in appetite 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Most common side effects	What to do
<ul style="list-style-type: none"> skin rash and itchiness <p>Reported in clinical trials with patients receiving IMFINZI in combination with tremelimumab:</p> <ul style="list-style-type: none"> underactive thyroid gland that can cause tiredness or weight gain abdominal pain diarrhoea abnormal pancreas test swelling of legs fever abnormal liver tests cough itchiness skin rash 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Some side effects can only be found when your doctor does blood tests from time to time to check your progress (for example, too much calcium in your blood, not enough sodium in your blood, not enough white blood cells, not enough red blood cells, not enough platelets, abnormal liver tests).

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of IMFINZI.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

IMFINZI is only available with a doctor's prescription.

What IMFINZI contains

Active ingredient (main ingredient)	durvalumab
Other ingredients (inactive ingredients)	histidine histidine hydrochloride monohydrate trehalose dihydrate polysorbate 80 water for injections

Do not take IMFINZI if you are allergic to any of these ingredients.

What IMFINZI looks like

IMFINZI concentrated solution for infusion is a clear to opalescent, colourless to slightly yellow liquid in a glass vial.

Australian Registration Number(s):

IMFINZI, 500 mg (500 mg/10mL) in 10 mL vial for intravenous infusion - AUST R 283216

IMFINZI, 120 mg (120 mg/2.4mL) in 10 mL vial for intravenous infusion - AUST R 283215

Who distributes IMFINZI

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone: 1800 805 342

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