

IMFINZI®

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.

1. Why am I using IMFINZI?

IMFINZI contains the active ingredient durvalumab. IMFINZI is used to treat several kinds 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.
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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.

IMFINZI®

Active ingredient(s): *durvalumab*

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 can be used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It may be prescribed to you:

- **in combination with chemotherapy that contains platinum prior to surgery (neoadjuvant treatment) and alone after surgery (adjuvant treatment) if:**
 - your cancer has spread within your lung and is able to be removed by surgery
- **alone if:**
 - your cancer has spread within your lung and cannot be removed by surgery, and
 - you have tried radiotherapy and chemotherapy that contains platinum, and your cancer has shrunk or has not worsened.

IMFINZI can be used to treat a type of lung cancer called small cell lung cancer (SCLC). It may be prescribed to you:

- **alone if:**
 - you have limited stage SCLC (LS-SCLC) and
 - your cancer has not been removed by surgery and
 - your cancer has responded or stabilised after initial treatment with radiotherapy and chemotherapy that contains platinum.
- **in combination with chemotherapy if:**
 - you have extensive stage SCLC (ES-SCLC) where 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 can be used to treat a type of cancer called biliary tract cancer (BTC), such as cancer of the bile ducts (cholangiocarcinoma) and gallbladder. It may be prescribed to you if:

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

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

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

IMFINZI can be used to treat a type of cancer of the lining of the uterus (endometrial cancer) that has spread beyond the original tumour or come back (recurred). It may be prescribed to you in combination with chemotherapy, followed by IMFINZI alone.

A test may be used to find out the mismatch repair (MMR) status of your endometrial cancer to help your doctor decide which treatment option may be the best for your cancer.

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 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 on the same day as chemotherapy, the IMFINZI infusion goes first, followed by chemotherapy.

When IMFINZI is given on the same day as tremelimumab, the tremelimumab infusion goes first, 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 (signs and symptoms)	What to do
<p>Problems with your lungs:</p> <ul style="list-style-type: none"> • lung inflammation that may include new or worse cough, shortness of breath, chest pain • chronic obstructive pulmonary disease 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious</p>

Serious side effects (signs and symptoms)	What to do
<p>(CO which causes the narrowing of airways and makes it difficult to breathe)</p> <ul style="list-style-type: none"> • lung infection (pneumonia) or influenza that may include cough or phlegm, fever, chills 	<p>side effects.</p> <p>Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next</p>

<p>Serious side effects (signs and symptoms)</p>	<p>What to do</p>
<p>and difficult to breathe</p> <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 	<p>dose of IMFINZI or stop your treatment with IMFINZI.</p>

Serious side effects (signs and symptoms)	What to do
<p>of stomach yellow of skin or white of eyes drowsy dark urine or bleeding or bruising more easily than normal</p> <p>Problems with your intestines</p>	

Serious side effects (signs and symptoms)	What to do
<ul style="list-style-type: none"> • inflammation of the intestines may include diarrhea or more frequent bowel movements than usual, black tarry sticky stools or stools with blood or mucous, severe stomach pain 	

Serious side effects (signs and symptoms)	What to do
<p>or tend</p> <p>Problems with some of your hormone glands</p> <ul style="list-style-type: none"> • inflammation of your hormone gland may include headache that will not go away or unusual 	

Serious side effects (signs and symptoms)	What to do
head extre tired weigh gain or weigh loss, dizzi or faint feelin more hung or thirs than usua hair loss, feelin cold cons char to your	

Serious side effects (signs and symptoms)	What to do
voice urina more often than usual naus or vom stom area (abd pain char in moo or beha such as decr sex drive incre anxie irrita	

Serious side effects (signs and symptoms)	What to do
<p>or forge fast and deep brea conf or a swee sme to your brea a swee or meta taste in your mou or a diffe odou</p>	<p>s,</p>

Serious side effects (signs and symptoms)	What to do
<p>to your urine or sweat</p> <p>Problem with your kidney</p> <ul style="list-style-type: none"> • inflammation of your kidney that may include changes in the amount or color of your urine 	<p>n</p>

Serious side effects (signs and symptoms)	What to do
<p>swelling in your ankles or loss of appetite</p> <p>Problems with your urinary tract:</p> <ul style="list-style-type: none"> • infection that may include the need to urinate urgently and frequently with burning 	

Serious side effects (signs and symptoms)	What to do
<p> pain or sensation when urinating bladder still feels full after urinating pain above your pubic bone blood in the urine </p> <p> Problems with your skin </p>	

Serious side effects (signs and symptoms)	What to do
or mouth <ul style="list-style-type: none"> • inflammation of the skin or mouth may include rash, itching, skin blisters or ulcers in the mouth or other mucous membranes. • thrush in 	

Serious side effects (signs and symptoms)	What to do
<p>the mouth</p> <p>Problem with your nose and throat</p> <ul style="list-style-type: none"> • nose or throat infection (sinus or tonsillitis) <p>Problem with your heart:</p> <ul style="list-style-type: none"> • inflammation of your heart may include 	

Serious side effects (signs and symptoms)	What to do
<p>chest pain shortness of breath or irregular heartbeat</p> <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/ 	<p>n</p>

Serious side effects (signs and symptoms)	What to do
<p>or rapid fatigue of the muscles in one or more areas of your body</p> <p>Problems with your blood:</p> <ul style="list-style-type: none"> • low number of blood platelets - may 	

Serious side effects (signs and symptoms)	What to do
<p>include bleeding (eg nose or gum bleed and/or bruising)</p> <p>Infusion related reactions</p> <ul style="list-style-type: none"> may include chills or shakiness, itching or rash, flushing, shortness of breath 	

Serious side effects (signs and symptoms)	What to do
<p>or wheezing, dizziness, fever, feeling like you are passing out, back or neck pain or facial swelling</p> <p>Encephalitis or meningitis</p> <ul style="list-style-type: none"> • may include seizure, neck stiffness, headache, fever 	

Serious side effects (signs and symptoms)	What to do
<p>chills vom eye sens to light conf and sleep</p> <p>Guillain-Barré syndrome</p> <ul style="list-style-type: none"> • may include pain, weakness and paraesthesia in the extremities <p>General body:</p> <ul style="list-style-type: none"> • an inflamed 	<p>y</p>

Serious side effects (signs and symptoms)	What to do
<p>respiratory distress that may include low or high body temperature, increased heart rate, increased breathing rate and/or abdominal white blood cell count</p> <p>Problems with your</p>	

Serious side effects (signs and symptoms)	What to do
immune system <ul style="list-style-type: none"> immune system attacks your red blood cells - signs and symptoms may include unusual weakness and fatigue with increased heart rate and breathing 	

Serious side effects (signs and symptoms)	What to do
<p> difficult yellow of the skin or white of the eyes (jaundice) dark urine and/ or an enlarged spleen </p> <p> Inflammation of the spinal cord: </p> <ul style="list-style-type: none"> • symptoms may 	

Serious side effects (signs and symptoms)	What to do
<p> include pain numb tingli or weak in the arms or legs blad or bowe prob inclu need to urina more frequ urina incor diffic urina </p>	<p>e,</p>

Serious side effects (signs and symptoms)	What to do
and cons	
Problems with your eyes: <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 	Contact a medical eye specialist (ophthalmologist) straight away, or go straight to the Emergency Department at your nearest hospital if you notice these side effects

Serious side effects (signs and symptoms)	What to do
in vision	effects as you may need urgent medical attention.

Most common side effects reported in clinical trials:

Most common side effects	What to do
Report in clinical trials with patient receiving	Speak to your doctor if you have any

Most common side effects	What to do to
IMFINZI alone: <ul style="list-style-type: none"> • cough • diarrhea • stomach pain • skin rash or itching • fever • swelling of the legs • upper respiratory tract infection • underactive thyroid gland that can cause tired 	of these side effects and they worry you.

Most common side effects	What to do
<p>or weight gain (hypothyroidism)</p> <ul style="list-style-type: none"> • overactive thyroid gland which may cause many different symptoms including weight loss, hand tremor, rapid or irregular heart 	
Report in a clinical trial with	Speak to your doctor if

Most common side effects	What do to
<p>patients you receive IMFINZI in combination with chemotherapy follow by IMFINZI alone:</p> <ul style="list-style-type: none"> • nausea • constipation • feeling tired or weak (fatigue) • skin rash and itching • decrease in appetite 	<p>you have any of these side effects, and they worry you.</p>

Most common side effects	What do to
<ul style="list-style-type: none"> • hair loss • diarrhea • inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs • cough • vomiting • underactive thyroid gland that can cause 	<p>n</p>

Most common side effects	What to do
tired or weight gain (hypothyroidism)	
Report in a clinical trial with patients receiving IMFINZI with etoposide and carboplatin or cisplatin <ul style="list-style-type: none"> • nausea • hair loss • decreased appetite • feeling tired 	Speak to your doctor if you have any of these side effects and they worry you.

Most common side effects	What to do to
or weakness (fatigue) • constipation • vomiting • cough	
Report in clinical trials with patients receiving IMFINZI with gemcitabine and cisplatin • low number of red blood cells (anaemia)	Speak to your doctor if you have any of these side effects and they worry you.

Most common side effects	What do to
<ul style="list-style-type: none"> • low number of white blood cells (neutrophils and leukocytes) • low number of blood platelets (thrombocytopenia) • diarrhea • stomach pain • constipation • nausea • vomiting • feeling tired or weak (fatigue) 	

Most common side effects	What to do to
<ul style="list-style-type: none"> • fever • abnormal liver function tests • decrease in appetite • skin rash and itching 	
Report in clinical trials with patients receiving IMFINZI in combination with tremelimumab: <ul style="list-style-type: none"> • under thyroid 	Speak to your doctor if you have any of these side effects: and they

Most common side effects	What to do
<p>glaucoma that can be caused by tiredness or weight gain</p> <ul style="list-style-type: none"> • stomach pain • diarrhoea • abdominal pain and pancreatic function tests • swelling of the legs • fever • abnormal liver function tests • cough 	<p>worry you.</p>

Most common side effects	What to do to
<ul style="list-style-type: none"> • skin rash or itching 	
<p>Report in a clinical trial with patient you receive IMFINZI in combination with carboplatin and paclitaxel follow by IMFINZI alone:</p> <ul style="list-style-type: none"> • low number of red blood 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Most common side effects	What do to
<p>cells (anaemia)</p> <ul style="list-style-type: none"> • nausea • feeling tired or weak (fatigue) • low number of white blood cells (neutropenia and leukopenia) • constipation • low number of platelets (thrombocytopenia) • diarrhoea • vomiting 	

Most common side effects	What do to
<ul style="list-style-type: none"> • stomach pain • decreased appetite • swelling of legs • underactive thyroid gland that can cause tired or weight gain (hypothyroidism) • abnormal liver function tests • muscle pain • inflammation of the 	

Most common side effects	What to do
nerve pain caused by numbness weakness tingling or burning pain of the arms and legs • cough production cough • hair loss • Skin rash or itching	

Some side effects can only be found when your doctor does blood tests from time to time to check your progress (eg abnormal thyroid gland function test (underactive or overactive), too much calcium in your

blood, not enough sodium in your blood, not enough white blood cells, not enough red blood cells, not enough blood platelets, abnormal liver function tests (eg aspartate aminotransferase (AST) increased; alanine aminotransferase (ALT) increased) or pancreas function tests).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other less common 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
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Other ingredients (inactive ingredients)	histidine histidine hydrochloride monohydrate trehalose dihydrate polysorbate 80 water for injections
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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
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