

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.

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.

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:**
 - o your cancer has spread within your lung and is able to be removed by surgery
- **alone if:**
 - o your cancer has spread within your lung and cannot be removed by surgery, and
 - o 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:**
 - o you have limited stage SCLC (LS-SCLC) and
 - o your cancer has not been removed by surgery and
 - o your cancer has responded or stabilised after initial treatment with radiotherapy and chemotherapy that contains platinum.
- **in combination with chemotherapy if:**
 - o you have extensive stage SCLC (ES-SCLC) where your cancer has spread within your lungs (or to other parts of the body) and
 - o 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.

IMFINZI is used to treat a type of bladder cancer called muscle-invasive bladder cancer (MIBC). It is used in combination with chemotherapy prior to the surgical removal of your bladder (neoadjuvant treatment) followed by IMFINZI alone after surgery (adjuvant treatment). It may be prescribed to you if:

- your cancer has spread into the muscle layer of the bladder but not to other parts of the body

IMFINZI can be used to treat a type of stomach cancer called gastric or gastroesophageal junction (GOJ) cancer that can be removed by surgery. It may be prescribed to you in combination with chemotherapy prior to surgery (neoadjuvant treatment) and after surgery (adjuvant treatment) followed by IMFINZI alone.

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 an autoimmune disease (a condition where the body attacks its own cells) like Crohn's disease, ulcerative colitis or lupus. If you already have an autoimmune disease, your risk of immune-mediated side effects may be higher with immune checkpoint inhibitor medicines (such as IMFINZI) as they may cause inflammation in parts of your body. You may also experience more frequent flares of your autoimmune disease, which in the majority of cases are mild
- have had an organ transplant
- have lung or breathing problems
- have liver problem
- have any other medical conditions
- 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 breastfeeding.

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.

When IMFINZI is given in combination with other anti-cancer medicines (eg chemotherapy or tremelimumab), 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 including side-effects, ask your doctor.

Serious side effects

Serious side effects (signs and symptoms)	What to do
Problems with your lungs: <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. Problems with your liver: <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. Problems with your intestines: <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. Problems with some of your hormone glands: <ul style="list-style-type: none"> inflammation of your hormone glands may include 	<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> <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 dose of IMFINZI or stop your treatment with IMFINZI.</p>

Serious side effects (signs and symptoms)	What to do
<p>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> <p>Problems with your kidneys:</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. <p>Problems with your urinary tract:</p> <ul style="list-style-type: none"> 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>	

Serious side effects (signs and symptoms)	What to do
<ul style="list-style-type: none"> inflammation of your muscles may include muscle weakness, tiredness and/or pain, and/or rapid fatigue of the muscles, in one or more areas of your body. <p>Problems with your blood:</p> <ul style="list-style-type: none"> low number of blood platelets - may include bleeding (eg 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 	

Serious side effects (signs and symptoms)	What to do
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 notice these side effects as you may need urgent medical attention.</p>

Immune checkpoint inhibitor class effects

There have been cases of the following serious side effects reported during treatment with other medicines in this class which may also occur during treatment with IMFINZI:

- decreased ability of the pancreas to make digestive enzymes, which may result in symptoms such as diarrhoea with loose and oily stools, weight loss, metabolic bone disease, and vitamin or mineral deficiencies (known as exocrine pancreatic insufficiency)
- decreased production of blood cells, which may result in symptoms such as weakness, shortness of breath, dizziness, fast or irregular heartbeat, frequent infections, unexplained or easy bruising, or bleeding from gums or other tissues (known as aplastic anaemia)
- a condition where the immune system makes too many infection-fighting cells which may result in symptoms such as an enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities and heart problems (known as haemophagocytic lymphohistiocytosis)
- coeliac disease which may result in symptoms such as stomach pain, diarrhoea and bloating after consuming gluten-containing foods)

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.

Most common side effects reported in clinical trials:

Most common side effects	What to do
<p>IMFINZI alone:</p> <ul style="list-style-type: none"> cough 	<p>Speak to your doctor if you</p>

Most common side effects	What do to
<ul style="list-style-type: none"> • diarrhoea • stomach pain • skin rash or itchiness • fever • swelling of the legs • upper respiratory tract infection • underactive thyroid gland that can cause tiredness or weight gain (hypothyroidism) • overactive thyroid gland which may cause many different symptoms including weight loss, hand tremors, rapid or irregular heartbeat 	<p>have any of these side effects and they worry you.</p>
<p>IMFINZI in combination with platinum-based chemotherapy [lung cancer]:</p> <ul style="list-style-type: none"> • nausea • constipation • feeling tired or weak (fatigue) • skin rash and itchiness • decrease in appetite • hair loss • diarrhoea • inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs • cough • vomiting • underactive thyroid gland that can cause tiredness or weight gain (hypothyroidism) 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>
<p>IMFINZI with chemotherapy (etoposide and carboplatin or cisplatin) [lung cancer]:</p> <ul style="list-style-type: none"> • nausea • hair loss • decreased appetite • feeling tired or weak (fatigue) • constipation • vomiting • cough 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>
<p>IMFINZI with chemotherapy (gemcitabine and cisplatin) [biliary tract cancer and/or bladder cancer]:</p> <ul style="list-style-type: none"> • low number of red blood cells (anaemia) • low number of white blood cells (neutropenia, lymphopenia and/or leukopenia) • low number of blood platelets (thrombocytopenia) • abnormal kidney function tests • diarrhoea • stomach pain 	<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
<ul style="list-style-type: none"> • constipation • nausea • vomiting • feeling tired or weak (fatigue) • fever • abnormal liver function tests • decrease in appetite • skin rash or itchiness • underactive thyroid gland that can cause tiredness or weight gain (hypothyroidism) • inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs 	
<p>IMFINZI in combination with chemotherapy (carboplatin and paclitaxel) [endometrial cancer]:</p> <ul style="list-style-type: none"> • low number of red blood cells (anaemia) • nausea • feeling tired or weak (fatigue) • low number of white blood cells (neutropenia and leukopenia) • constipation • low number of blood platelets (thrombocytopenia) • diarrhoea • vomiting • stomach pain • decreased appetite • swelling of legs • underactive thyroid gland that can cause tiredness or weight gain (hypothyroidism) • abnormal liver function tests • muscle pain • inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs • cough / productive cough • hair loss • skin rash or itchiness 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>
<p>IMFINZI in combination with chemotherapy (FLOT - fluorouracil, leucovorin, oxaliplatin and docetaxel) [stomach cancer] :</p> <ul style="list-style-type: none"> • low number of white blood cells (neutropenia and leukopenia) • low number of red blood cells (anaemia) • low number of blood platelets (thrombocytopenia) • diarrhoea • nausea • vomiting 	<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
<ul style="list-style-type: none"> stomach pain inflammation of the mouth or lips constipation feeling tired or weak (fatigue) fever decreased appetite inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs hair loss skin rash or itchiness lung infection (pneumonia) that may include coughing of phlegm, fever, chills and difficulty breathing cough 	
IMFINZI in combination with tremelimumab [hepatocellular cancer]: <ul style="list-style-type: none"> underactive thyroid gland that can cause tiredness or weight gain stomach pain diarrhoea abnormal pancreas function test swelling of the legs fever abnormal liver function tests cough skin rash or itchiness 	Speak to your doctor if you have any of these side effects and they worry you.

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), high calcium level, low sodium level, low number of white blood cells, low number of red blood cells, low number of blood platelets, abnormal liver function tests (eg aspartate aminotransferase (AST) increased; alanine aminotransferase (ALT) increased) or pancreas function tests or kidney function tests (eg blood creatinine increased)).

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
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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