



IMFINZI[®] (durvalumab) PATIENT INFORMATION

**for Stage III unresectable
non-small cell lung cancer (NSCLC)**

This booklet has been developed for use by adult patients with Stage III (locally advanced), unresectable non-small cell lung cancer who have been prescribed IMFINZI.

This booklet is not a substitute for the professional advice of your doctor/specialist or the IMFINZI Consumer Medicine Information (CMI). Please ask your Cancer Care Team or your pharmacist for a copy of the IMFINZI CMI.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. You can let your doctor know about any side effects you may experience and the doctor can report them via <https://pophealth.my.site.com/carmreportnz/s/>



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What is Stage III (locally advanced) unresectable non-small cell lung cancer (NSCLC)?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer.¹ About 80% people who are diagnosed with lung cancer have the non-small cell lung cancer type.¹

Stage III NSCLC refers to cancer that has spread from its original position within the lung:^{1,2}

- to other areas in the lung and/or to lymph nodes in the chest area, or
- to the area of the chest immediately surrounding the lung(s).

This is also known as locally advanced NSCLC. If it has spread to other areas in the body outside of the lung, the cancer is referred to as metastatic, rather than locally advanced.¹



What is IMFINZI and why has it been prescribed to you?

IMFINZI is a type of cancer treatment called immunotherapy.³ Immunotherapy stimulates your body's immune system to find and attack cancer cells.^{3,4}

It's important to note that **IMFINZI is not chemotherapy.**

IMFINZI has been prescribed to you because it is a treatment option for a type of lung cancer called Stage III, unresectable NSCLC.^{3,5} IMFINZI is usually given shortly after you have completed your chemotherapy and radiation treatment where your cancer has responded to treatment or is considered stabilised.^{3,5}



Please remember that the information in this booklet does not replace information or advice provided by your Cancer Care Team. If you have any concerns about receiving IMFINZI, please speak to your Cancer Care Team.

How does IMFINZI work?

To understand how IMFINZI works, it's important to understand your body's immune system and cancer. They are:



Healthy cell



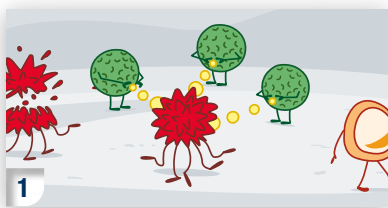
Immune system



Cancer cell

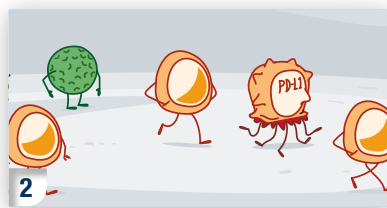


IMFINZI



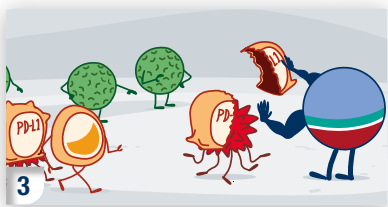
The immune system helps protect the body from things that are harmful, including cancer cells.

When cancer cells appear in your body, your immune system works to recognise and attack them.⁴

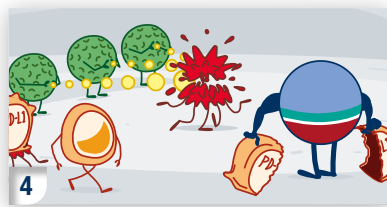


Sometimes, cancer cells can disguise themselves and go undetected by the immune system.⁴

PD-L1 is a protein in your body that cancer cells can use to disguise themselves from the immune system.⁴



IMFINZI works by blocking PD-L1 to remove the disguise so your immune system can detect the cancer cells.³⁻⁵



The immune system can then mount an attack against the cancer cells. There is a chance that IMFINZI may affect healthy cells too.^{3,4} See page 9 or talk to your Cancer Care Team for more information.

How will you receive IMFINZI?



IMFINZI is a liquid infusion into your vein (IV)³

The infusion usually takes about 60 minutes³

You receive an infusion every 2 or 4 weeks³

Keep in mind:

- **Your doctor will decide how many treatments you need.³**
- Usually, you will receive your infusion at your hospital or an infusion centre. Your Cancer Care Team will supply your IMFINZI. You won't have to go to the pharmacy to pick up your medicine.
- Your Cancer Care Team will monitor you for side effects. You will need to have blood tests before starting IMFINZI and periodically during treatment. If you feel unwell you should notify a member of your Cancer Care Team immediately. The sooner side effects are picked up, the quicker they may be managed.^{3,5}



If you miss any appointments, call your Cancer Care Team as soon as possible to reschedule.

How long will you need to take IMFINZI for?

Every person is different. Your doctor will decide for how long you will receive IMFINZI.³

What should you tell your Cancer Care Team before receiving IMFINZI?

Before you receive IMFINZI, tell your doctor about all of your medical conditions, including if you:^{3,5,6}

- Have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- Have had an organ transplant
- Have lung or breathing problems
- Have been given oral steroid therapy for lung, kidney or skin problems
- Have thyroid problems
- Have liver problems
- Have type 1 diabetes mellitus
- Have pituitary gland problems
- Are being treated for an infection
- Have hypersensitivity / allergic reactions to durvalumab, other medicines, foods, or any other ingredients listed in the CMI
- Are pregnant or plan to become pregnant:
 - IMFINZI may affect your developing baby if you take it during pregnancy
 - Tell your doctor right away if you become pregnant during treatment with IMFINZI
 - 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. Talk to your doctor about which birth control methods to use
- Are breastfeeding or plan to breastfeed:
 - It is not known if IMFINZI passes into breast milk, but if it does, there is a possibility that your baby may be affected
 - Do not breastfeed during treatment and for at least 3 months after the last dose of IMFINZI



This information may help guide your Cancer Care Team on how best to monitor you during treatment.

Tell your Cancer Care Team and other healthcare professionals about all the medicines you take. This includes prescription and over-the-counter medicines, vitamins and herbal supplements.³

What to expect during your IMFINZI infusion?

Bring a list of any questions you have for your Cancer Care Team. They will be around to check on you during your treatment, so it's a good time to get answers to your questions.

IMFINZI is unlikely to affect your ability to drive or operate machines. However, some people may experience a side effect that affects their ability to concentrate and react. You might like to organise transport to and from your infusion in case you are unable to drive afterwards.^{3,5}

While getting your infusion, keep an eye out for any of these signs or symptoms.³

- Chills or shaking
- Itching or rash
- Flushing
- Shortness of breath or wheezing
- Dizziness
- Fever
- Feeling like passing out
- Back or neck pain
- Facial swelling



If you have any of these, talk to the Cancer Care Team monitoring your infusion immediately as some of these symptoms may signal that you are having a reaction to your medicine.³



Why do some patients have side effects from IMFINZI?

All medicines can have side effects. IMFINZI works with your immune system to help it find and attack the lung cancer cells.^{3,4}

Treatment with IMFINZI can cause your immune system to attack healthy organs and tissues in many areas of your body, affecting how they work. This can cause side effects. These side effects are called immune-mediated adverse reactions (imARs) and can become serious or life-threatening if not managed quickly.³⁻⁶



It is important to notify your Cancer Care Team immediately if you notice a change or worsening in your health or wellbeing during and after IMFINZI treatment. Alerting your Cancer Care Team early means they can start managing your side effects sooner, which may be able to prevent these side effects from becoming more serious.^{3,5}

How do you recognise side effects?

While you are on IMFINZI, you will need to look out for any signs or symptoms of side effects. You can read more information about common or potentially serious side effects associated with IMFINZI treatment in the next sections of this booklet.

Keep in mind how you felt just before you started treatment with IMFINZI as you may already be experiencing side effects from your cancer or previous treatments.



Record details of how you felt before starting treatment with IMFINZI so that you and your Cancer Care Team can refer back to your notes later when monitoring for signs of side effects.

There is a space on your **IMFINZI Patient Alert Card** and on **page 15** of this booklet for you to record this information.

Identify your side effects early so they may be managed before they may become more serious.

Keep track of how you're feeling on a daily basis. Sometimes a mild side effect can lead to something more serious if not treated.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

What are the most common side effects that may occur while taking IMFINZI?³



Cough



Fever



Skin rash or itchiness



Stomach pain, diarrhoea



Swellings of the legs



Underactive thyroid gland that can cause tiredness or weight gain



Upper respiratory infection

It's very important to tell your Cancer Care Team if you experience ANY side effects, changes or anything else that is worrying you.

Record the contact details for key members of your Cancer Care Team below.

My doctor (oncologist):

Oncologist's out of hours clinic contact:

My cancer specialist nurse:

My infusion nurse or other key contact:

What are the serious side effects to act on straight away?

Contact your Cancer Care Team straight away if you notice any signs and symptoms of the side effects listed below that may occur while taking IMFINZI.³

Do not attempt to treat any side effects without talking to your Cancer Care Team first.

SIGNS AND SYMPTOMS OF SERIOUS SIDE EFFECTS THAT REQUIRE URGENT MEDICAL ATTENTION³



INFLAMMATION OF THE INTESTINES (COLITIS)

- Diarrhoea
- More bowel movements than usual
- Black, tarry, sticky stools
- Stools with blood or mucus
- Severe stomach pain or tenderness



INFLAMMATION OF THE LUNGS (PNEUMONITIS)

- New or worsening cough
- Shortness of breath
- Chest pain



LUNG INFECTION (PNEUMONIA, INFLUENZA)

- Coughing of phlegm
- Fever
- Chills
- Difficulty breathing



INFLAMMATION OF THE LIVER (HEPATITIS)

- Yellowing of your skin or the whites of your eyes
- Nausea or vomiting
- Pain on the right side of stomach
- Feeling less hungry
- Drowsiness
- Dark urine
- Bleeding or bruising more easily than normal

SIGNS AND SYMPTOMS OF SERIOUS SIDE EFFECTS THAT REQUIRE URGENT MEDICAL ATTENTION³



HORMONE GLAND PROBLEMS (ESPECIALLY THE THYROID, ADRENALS AND PITUITARY)

- 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 in 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
- Sweet smell to your breath, sweet or metallic taste in your mouth or different odour to your urine or sweat



INFLAMMATION OF THE KIDNEYS (NEPHRITIS)

- Changes in the amount or colour of your urine
- Swelling in your ankles
- Loss of appetite



URINARY TRACT PROBLEMS (INFECTION)

- 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 your urine



INFLAMMATION OF THE SKIN OR MOUTH

- Rash
- Itching
- Skin blistering
- Ulcers in the mouth or other mucous membranes
- Thrush in the mouth



NOSE OR THROAT INFECTION

- Sinusitis
- Tonsillitis

SIGNS AND SYMPTOMS OF SERIOUS SIDE EFFECTS THAT REQUIRE URGENT MEDICAL ATTENTION³



INFLAMMATION OF THE HEART (MYOCARDITIS)

- Chest pain
- Shortness of breath
- Irregular heartbeat



INFLAMMATION OF THE MUSCLES

- Muscle weakness
- Tiredness and/or pain
- Rapid fatigue of the muscles, in one or more areas of your body



LOW NUMBER OF PLATELETS

- Bleeding (eg. nose or gum bleeding)
- Bruising



INFUSION-RELATED REACTIONS

- Chills or shaking
- Itching or rash
- Flushing
- Shortness of breath or wheezing
- Dizziness
- Fever
- Feeling like passing out
- Back or neck pain
- Facial swelling



INFLAMMATION OF THE SPINAL CORD

- Pain, numbness, tingling, or weakness in arms or legs
- Bladder/bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation

SIGNS AND SYMPTOMS OF SERIOUS SIDE EFFECTS THAT REQUIRE URGENT MEDICAL ATTENTION³



INFLAMMATION OF THE BRAIN OR MEMBRANES AROUND THE BRAIN/SPINAL CORD (ENCEPHALITIS/MENINGITIS)

- Seizures
- Neck stiffness
- Headache
- Fever
- Chills
- Vomiting
- Eye sensitivity to light
- Confusion
- Sleepiness



GUILLAIN-BARRÉ SYNDROME

- Pain
- Weakness
- Paralysis in the hands, feet or arms



GENERAL BODY INFLAMMATORY RESPONSE

- Low or high body temperature
- Increased heart rate
- Increased breathing rate
- Abnormal white blood cell count



PROBLEMS WITH YOUR IMMUNE SYSTEM (IMMUNE SYSTEM ATTACKING RED BLOOD CELLS)

- 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



INFLAMMATION OF THE EYES (UVEITIS)

- Eye redness
- Eye pain
- Light sensitivity
- Changes in vision



ARTHRITIS

- Joint pain, swelling, and/or stiffness



Getting medical treatment as soon as possible may help keep these side effects from becoming more serious^{3,5}

Your Cancer Care Team will monitor you for these side effects during your treatment with IMFINZI.

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.⁵

Ask your Cancer Care Team for more information.

Keeping important safety information at hand

If you visit the emergency room or a healthcare professional who is not part of your regular Cancer Care Team, it's important to tell them that you are being treated with an immunotherapy, which is different from chemotherapy.

Three tips to make sure you get the appropriate care:

1. Ideally before you start treatment with IMFINZI, fill out the **IMFINZI Patient Alert Card** (attached below) and keep it with you at all times.
2. Even after you stop treatment, keep the card with you because side effects can still happen after treatment has finished.
3. If you have a phone with a camera, take a picture of the **IMFINZI Patient Alert Card** just in case you leave the card at home.

IMFINZI® (durvalumab) Patient Alert Card

**I AM RECEIVING
IMMUNOTHERAPY**

Fill out the information inside and carry this card with you at all times to share with healthcare professionals (including your GP, Accident and Emergency team or other specialist doctor).

YOUR IMFINZI PATIENT ALERT CARD

If your **IMFINZI Patient Alert Card** is missing, please ask your Cancer Care Team for another one.

More information

Your Cancer Care Team is your best source of information about your treatment. In addition, the following support groups may also be of interest:

Lung Foundation New Zealand



(+64) 021 959 450



lungfoundation.org.nz

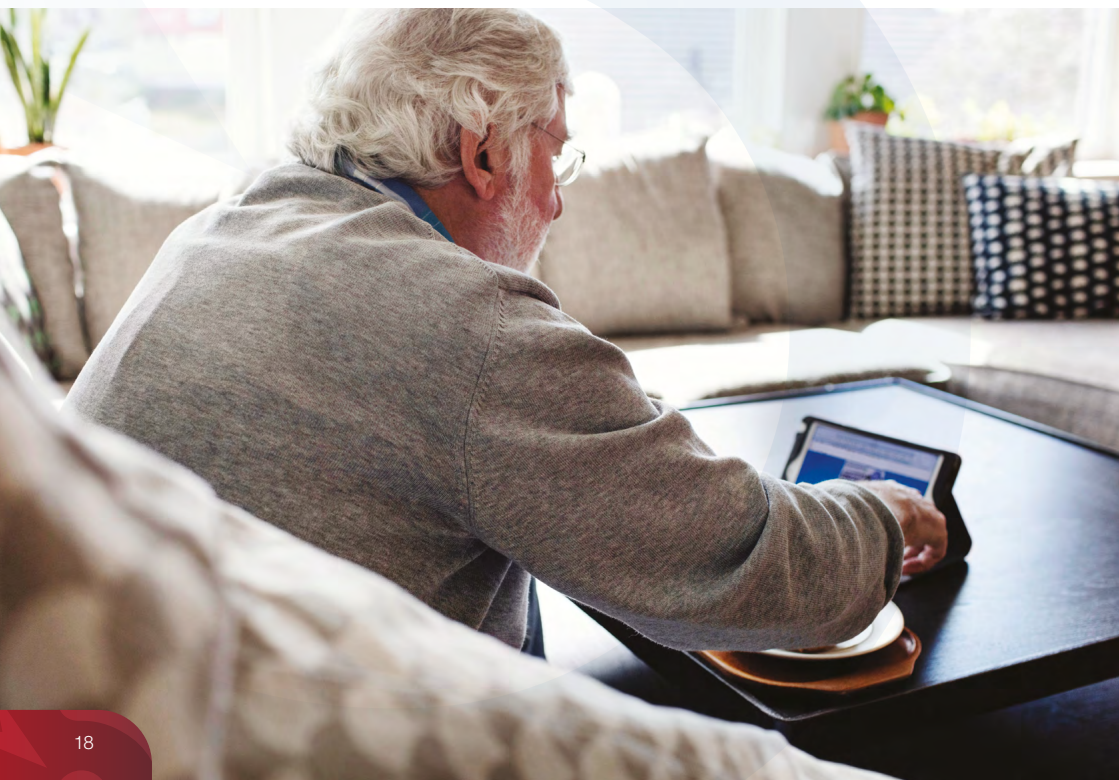
Cancer Society of New Zealand



0800 226 237







cancer.org.nz



Recognise how you feel now

Record details of how you felt *before* starting treatment with IMFINZI so that you and your Cancer Care Team can refer back to these details later when monitoring for signs of side effects. This information should also be recorded on your alert card.

What's normal for me?

 BOWEL MOVEMENTS I usually have: _____ bowel movements per day	 SHORTNESS OF BREATH My breathing usually disrupts my daily activities:  A little A lot	 TIREDNESS I usually sleep: _____ hours a day
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 **Contact your Cancer Care Team if you notice any changes in these or other symptoms during treatment with IMFINZI.**

 PAIN On a scale of 1–10 my pain is usually: _____ (where 10=severe)	My pain usually lasts: _____ hours	I would normally describe my pain as: _____ _____ _____
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OTHER SIGNS OF SIDE EFFECTS RELATED TO MY CANCER OR PREVIOUS TREATMENT

Side effects I usually experience:*

MY NORMAL PHYSICAL ACTIVITIES ARE:

*Remember, you may experience some side effects prior to starting treatment with IMFINZI. These may be related to your cancer or previous treatment you received.



Contact your Cancer Care Team if you notice any changes in these or other symptoms during treatment with IMFINZI.

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



A series of horizontal blue lines for writing, spanning the width of the page. The lines are evenly spaced and cover most of the page area, except for the header and footer.





IMFINZI® Abridged Information for Consumers IMFINZI vials contain 50 mg/mL durvalumab concentrated solution for infusion. IMFINZI is a Prescription Medicine. **Imfinzi is used to treat (under certain requirements):** Urothelial carcinoma (a type of bladder cancer), two types of lung cancer called Non-Small Cell Lung Cancer and Extensive-Stage Small Cell Lung Cancer, and biliary tract cancer (cancer of the bile ducts and gallbladder). IMFINZI will be given with chemotherapy for Extensive-Stage Small Cell Lung Cancer and biliary tract cancer. **Do not use if** allergic to durvalumab or any of the ingredients, pregnant or breastfeeding. **Before being given IMFINZI, tell your doctor if you have** allergies, immune system problems such as Crohn's disease, ulcerative colitis or lupus, had an organ transplant, lung or breathing problems, liver problems and if you are taking other medicines, including those you buy from a pharmacy, supermarket or health food shop. Tell your doctor if you are pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed. Whilst being given IMFINZI, tell your doctor if you become pregnant. 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. Do not breastfeed if you are being given IMFINZI and for at least 3 months after the last dose. **Possible side effects:** Cough, diarrhoea, stomach pain, skin rash or itchiness, fever, swelling of legs, upper respiratory tract infection, underactive thyroid gland that can cause tiredness or weight gain, neutropenia and leukopenia (low number of white blood cells), anaemia (low number of red blood cells), thrombocytopenia (low number of platelets), nausea, hair loss, feeling tired or weak, constipation, decreased appetite, vomiting, abnormal liver tests. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice: Lung inflammation may include new or worsening cough, shortness of breath, chest pain; Lung infection (pneumonia or influenza) may include coughing of phlegm, fever, chills and difficulty breathing; Inflammation of liver may include nausea and vomiting, feeling less hungry, pain on right side of stomach, yellowing of skin or whites of eyes, drowsiness, dark urine, bleeding or bruising more easily than normal; Inflammation of intestines may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucus, severe stomach pain or tenderness; Inflammation of hormone glands; Urinary tract infection; Inflammation of heart may include chest pain, shortness of breath or irregular heartbeat; Inflammation of kidneys may include changes in the amount or colour of urine, swelling in ankles, loss of appetite; Inflammation of skin or mouth; Nose and throat infection; Inflammation of muscles; Infusion related reactions; Encephalitis or Meningitis may include seizures, neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness. Guillain-Barré syndrome may include pain, weakness, and paralysis in hands, feet or arms; Inflammatory response in general body may include low or high body temperature, increased heart rate, increased breathing rate and/or abnormal white blood cell count; Problems with immune system: 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; Inflammation of spinal cord 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; Inflammation of joints may include joint pain, swelling, and/or stiffness; Inflammation of eyes (uveitis) may include eye redness, eye pain, light sensitivity, and/or changes in vision. Some side effects can only be found out through tests. Ask your doctor if IMFINZI is right for you. IMFINZI has risks and benefits. Use strictly as directed. If symptoms continue or you have side effects, see your doctor, pharmacist or health professional. IMFINZI is funded on the Pharmaceutical Schedule for non-small cell lung cancer under special authority criteria. Your doctor's fee and prescription charges will apply. For full consumer information please refer to the manufacturer's Consumer Medicine Information available at www.medsafe.govt.nz

References: 1. Cancer Society of New Zealand Inc. Lung Cancer - A guide for people with lung cancer. Available at <https://www.cancer.org.nz/cancer/types-of-cancer/lung-cancer/> (accessed March 2024). 2. Lung Foundation Australia. <https://lungfoundation.com.au/patients-carers/conditions/lung-cancer/stages/> (accessed March 2024). 3. IMFINZI® Consumer Medicine Information. 4. National Comprehensive Cancer Network (NCCN). Immunotherapy side effects. Immune checkpoint inhibitors. NCCN guidelines for patients, 2022. Available at: <https://www.nccn.org/patientresources/patient-resources/guidelines-for-patients/guidelines-for-patients-details?patientGuidelineId=46> (accessed March 2024). 5. IMFINZI® Data Sheet. 6. Champiat S, et al. *Ann Oncol* 2016;27(4):569-574.



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