

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

 **IMFINZI® (im-FIN-zee)**  
**durvalumab for injection, intravenous infusion**

Read this information carefully before you start treatment with **IMFINZI** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **IMFINZI**.

**What is IMFINZI used for?**

IMFINZI (durvalumab) is a medicine used to treat adults with a bladder cancer (called urothelial carcinoma) including cancer of the ureter, urethra or kidney pelvis. It is used when:

- Your cancer has spread and cannot be removed by surgery and,
- You have received chemotherapy, and it did not work or is no longer working.

IMFINZI is also used to treat adults with a type of lung cancer called non-small cell lung cancer. It is used when:

- Your cancer has grown within your lung and cannot be removed by surgery and,
- Your cancer has responded or stabilized after treatment with chemotherapy and radiation therapy.

IMFINZI contains the active substance durvalumab which belongs to the monoclonal antibody class of anticancer medicines. Refer to the NOC/c summary box below for additional detail.

For the following indications IMFINZI has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

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- Your cancer has responded or stabilized after treatment with chemotherapy and radiation therapy.

**What is a Notice of Compliance with Conditions (NOC/c)?**

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

### **How does IMFINZI work?**

- IMFINZI works by helping your immune system fight your cancer.
- IMFINZI can help slow or stop your cancer from growing. It can also help shrink the tumour.
  - The average time to respond to IMFINZI for a bladder cancer patient is approximately 1.5 months. However, this may vary from patient to patient.

If you have any questions about how IMFINZI works or why this medicine has been prescribed for you, ask your healthcare professional.

### **What are the ingredients in IMFINZI?**

Medicinal ingredient: durvalumab.

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate,  $\alpha,\alpha$ -trehalose dihydrate, polysorbate 80, and water for injection.

### **IMFINZI comes in the following dosage forms:**

A solution in 10 mL single-use glass vials containing either 2.4 mL or 10 mL of 50 mg/mL durvalumab. After further dilution and preparation, IMFINZI is administered as an intravenous infusion.

### **Do not use IMFINZI if:**

- You are allergic to durvalumab or any other ingredients in IMFINZI.

**To help avoid unnecessary side effects and ensure proper use, talk to your healthcare professional before you take IMFINZI. Talk about any health conditions or problems you may have, including 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
- Have problems with hormone producing glands such as your thyroid, pituitary, adrenal glands or pancreas
- Have diabetes
- Are taking medicine(s) that affect the immune system such as a steroid

**If you have any questions about your medical condition, talk to your healthcare professional.**

### **When you receive IMFINZI, you can have some serious side effects.**

IMFINZI can cause your immune system to attack normal organs and tissues in your body and can affect the way they work.

## **Other warnings you should know about:**

### **Pregnancy**

- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor before taking this medicine. You should not use IMFINZI if you are pregnant.
- IMFINZI can harm your unborn baby.
- If you are a woman who could 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.

### **Breastfeeding**

- If you are breastfeeding or plan to breastfeed, tell your doctor.
- Do not breastfeed during treatment and for at least 3 months after the last dose of IMFINZI. It is not known if IMFINZI passes into your breast milk.

### **Driving and using machines**

If you experience side effects affecting your ability to concentrate and react, do not drive or use machines until you feel better.

**Tell your healthcare professional about all the medicines you take, have recently taken or might take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **How to take IMFINZI:**

- IMFINZI will be given to you in a hospital or clinic under the supervision of an experienced healthcare professional. Your healthcare professional will give you IMFINZI through an intravenous infusion into your vein for about 60 minutes.
- IMFINZI is typically given every 2 weeks.
- Your doctor will decide how many treatments you need.

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

### **Usual dose:**

The recommended dose is 10 mg of durvalumab per kilogram of your body weight.

It is not known if IMFINZI is safe and effective in children less than 18 years of age.

### **Overdose:**

If you think you have been given too much IMFINZI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

### **Missed Dose or Appointment to get IMFINZI:**

It is very important that you keep all your appointments to get IMFINZI. If you miss an appointment, call your doctor as soon as possible to discuss next steps.

### **What are possible side effects from using IMFINZI?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are not all the possible side effects you may feel when taking IMFINZI. If you get any side

effects, talk to your doctor, pharmacist or nurse. If you experience any side effects not listed here, contact your healthcare professional.

The following side effects have been reported in clinical trials with IMFINZI in patients with bladder cancer:

Most frequent serious side effects:

- urinary tract infection
- acute kidney injury
- back pain
- general physical health deterioration

Very common side effects ( $\geq 10\%$ ):

- feeling tired
- decreased appetite
- diarrhea
- joint pain
- fever
- feeling sick (nausea)
- cough
- difficulty breathing
- rash or itchiness
- constipation

The following side effects have been reported in clinical trials with IMFINZI in patients with lung cancer:

Most frequent serious side effects:

- lung infection
- lung inflammation

Very common side effects ( $\geq 10\%$ ):

- cough
- upper respiratory tract infection
- rash
- diarrhea
- fever

When you get IMFINZI, you can have some serious side-effects. See table below. If you have any of the following, call or see your healthcare professional right away. Your healthcare professional may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your healthcare professional may withhold the next dose of IMFINZI or stop your treatment with IMFINZI.

<b>Serious side effects and what to do about them</b>		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
<p><b>Lung inflammation (pneumonitis).</b> Signs and symptoms of pneumonitis may include:</p> <ul style="list-style-type: none"> <li>• new or worsening cough</li> <li>• shortness of breath</li> <li>• chest pain</li> </ul>		√
<p><b>Liver problems (hepatitis).</b> Signs and symptoms of hepatitis may include:</p> <ul style="list-style-type: none"> <li>• yellowing of your skin or the whites of your eyes</li> <li>• severe nausea or vomiting</li> <li>• pain on the right side of your stomach area (abdomen)</li> <li>• drowsiness</li> <li>• dark urine (tea coloured)</li> <li>• bleeding or bruising more easily than normal</li> <li>• feeling less hungry than usual</li> </ul>		√
<p><b>Intestinal problems (colitis) that can lead to tears or holes in your intestine.</b> Signs and symptoms of colitis may include:</p> <ul style="list-style-type: none"> <li>• diarrhea or more bowel movements than usual</li> <li>• stools that are black, tarry, sticky, or have blood or mucus</li> <li>• severe stomach area (abdomen) pain or tenderness</li> </ul>		√
<p><b>Hormone gland problems (especially the thyroid, adrenals, pituitary and pancreas).</b> Signs and symptoms that your hormone glands especially the thyroid gland is not working properly may include:</p> <ul style="list-style-type: none"> <li>• headaches that will not go away or unusual headaches</li> <li>• extreme tiredness</li> <li>• weight gain or weight loss</li> <li>• dizziness or fainting</li> <li>• feeling more hungry or thirsty than usual</li> <li>• hair loss</li> <li>• feeling cold</li> <li>• constipation</li> <li>• changes to your voice</li> <li>• urinating more often than usual</li> </ul>		√

<b>Serious side effects and what to do about them</b>		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
<ul style="list-style-type: none"> <li>• nausea or vomiting</li> <li>• stomach area (abdomen) pain</li> <li>• changes in mood or behaviour, such as decreased sex drive, irritability, or forgetfulness</li> </ul>		
<p><b>Kidney problems, including inflammation (nephritis) and kidney failure.</b></p> <p>Signs of kidney problems may include:</p> <ul style="list-style-type: none"> <li>• decrease in the amount of urine</li> <li>• blood in your urine</li> <li>• swelling in your ankles</li> <li>• loss of appetite</li> </ul>		√
<p><b>Skin or mouth problems.</b></p> <p>Signs of these problems may include:</p> <ul style="list-style-type: none"> <li>• rash</li> <li>• itching</li> <li>• skin blistering</li> <li>• ulcers in mouth or other mucous membranes</li> </ul>		√
<p><b>Problems in other organs.</b></p> <p>Signs of these problems may include:</p> <ul style="list-style-type: none"> <li>• changes in eyesight</li> <li>• severe or persistent muscle or joint pains</li> <li>• chest pain, shortness of breath, irregular heartbeat (myocarditis)</li> </ul>		√
<p><b>Muscle problems.</b></p> <p>Signs of these problems may include:</p> <ul style="list-style-type: none"> <li>• severe muscle weakness</li> <li>• tiredness</li> <li>• pain in one or more areas of your body</li> </ul>		√
<p><b>Severe infusion reactions.</b></p> <p>Signs and symptoms of severe infusion reactions may include:</p> <ul style="list-style-type: none"> <li>• chills or shaking</li> <li>• itching or rash</li> <li>• flushing</li> <li>• shortness of breath or wheezing dizziness</li> <li>• fever</li> <li>• feeling like passing out</li> <li>• back or neck pain</li> <li>• facial swelling</li> </ul>		√

If you have a side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## Storage of IMFINZI for Healthcare Professional:

IMFINZI should not be used after the expiry date which is stated on the label and carton. IMFINZI should be stored in a refrigerator (2° to 8°C) in the original package in order to protect from light. Do not freeze or shake. Any unused medicine or waste material should be disposed of in accordance with local requirements.

Keep medication out of reach and sight of children.

## If you want more information about IMFINZI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(http://hc-sc.gc.ca/index-eng.php\)](http://hc-sc.gc.ca/index-eng.php); the manufacturer's website [www.astrazeneca.ca](http://www.astrazeneca.ca), or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at [www.astrazeneca.ca](http://www.astrazeneca.ca).

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