

# IMFINZI®

Duvalumab, 50 mg/mL, concentrated solution for infusion

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some of the common questions people ask about **Imfinzi**. It does not contain all the information that is known about **Imfinzi**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Imfinzi** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

### What Imfinzi is used for

**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.

This medicine is used to treat urothelial carcinoma, a type of bladder cancer. It will be prescribed to you if:

- your cancer has spread and cannot be removed by surgery and;
- you have tried chemotherapy that contains platinum, and it did not work or is no longer working. You may have had the chemotherapy just before or during another treatment such as radiation.

This medicine is also used to treat a type of lung cancer called Non-Small Cell Lung Cancer. 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.

This medicine is also used to treat a type of lung cancer called Extensive-Stage Small Cell Lung Cancer. 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** will be given in combination with chemotherapy for this indication. It is important that you also read the consumer leaflets for the specific chemotherapy you will be receiving. If you have any questions about these medicines, ask your doctor.

**Imfinzi** is used to treat a type of cancer called biliary tract cancer (BTC), such as cancer of the bile ducts 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** will be given in combination with chemotherapy for this indication. It is important that you also read the consumer leaflets for the specific chemotherapy you will be receiving. If you have any questions about these medicines, ask your doctor.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

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

### Before you are given Imfinzi

#### **When you must not be given this medicine**

You should not be given this medicine if you have an allergy to:

Imfinzi® CMI 020223

- durvalumab or any of the ingredients listed at the end of this leaflet.

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.

**You should not be given this medicine if you are pregnant.** It may affect your developing baby if you use it during pregnancy.

**You should not be given this medicine 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.

If you are not sure whether you should be given this medicine, talk to your doctor.

### **Before you are given this medicine**

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding or plan to breast-feed. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you are given **Imfinzi**.

### **Taking other medicines**

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

## **How Imfinzi is given to you**

**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.

Your doctor will decide how many treatments you need.

### **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 this medicine.

## **While you are being treated with Imfinzi**

### **Things you must do**

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are a woman who could become pregnant, you must use adequate birth control while you are being treated with this medicine and for at least 3 months after your last dose.

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

### **Things you must not do**

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

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.

**Side effects**

This medicine may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**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.

**Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Signs and symptoms of problems with your lungs:</b></p> <ul style="list-style-type: none"> <li>• new or worsening cough, shortness of breath, chest pain</li> <li>• coughing of phlegm, fever, chills and difficulty breathing.</li> </ul> <p><b>Signs and symptoms of problems with your liver:</b></p> <ul style="list-style-type: none"> <li>• nausea or vomiting</li> <li>• feeling less hungry</li> <li>• pain on the right side of stomach</li> <li>• yellowing of skin or whites of eyes</li> <li>• drowsiness</li> <li>• dark urine</li> <li>• bleeding or bruising more easily than normal.</li> </ul> <p><b>Signs and symptoms of problems with your intestines:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea or more bowel movements than usual</li> <li>• black, tarry, sticky stools or stools with blood or mucous</li> <li>• severe stomach pain or tenderness.</li> </ul> <p><b>Signs and symptoms of problems with your hormone glands:</b></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, nausea or vomiting</li> <li>• stomach area (abdomen) pain</li> <li>• changes in mood or behaviour, such as decreased sex drive, increased anxiety, irritability or forgetfulness</li> <li>• fast and deep breathing</li> <li>• confusion</li> <li>• sweet smell to your breath</li> <li>• sweet or metallic taste in your mouth</li> <li>• different odour to your urine or sweat.</li> </ul> <p><b>Signs and symptoms of problems with your kidney:</b></p> <ul style="list-style-type: none"> <li>• changes in the amount or colour of your urine</li> <li>• swelling in your ankles</li> <li>• loss of appetite.</li> </ul> <p><b>Signs and symptoms of problems with your urinary tract:</b></p> <ul style="list-style-type: none"> <li>• the need to urinate urgently and frequently</li> <li>• burning pain or sensation when urinating</li> <li>• bladder still feels full after urinating</li> <li>• pain above your pubic bone</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<p>• blood in the urine.</p> <p><b>Signs and symptoms of problems with your heart:</b></p> <ul style="list-style-type: none"> <li>• chest pain, shortness of breath or irregular heartbeat.</li> </ul> <p><b>Signs and symptoms of problems with your skin or mouth:</b></p> <ul style="list-style-type: none"> <li>• rash</li> <li>• itching</li> <li>• skin blistering</li> <li>• ulcers in the mouth or other mucous membranes</li> <li>• thrush in the mouth.</li> </ul> <p><b>Signs and symptoms of problems with your nose and throat:</b></p> <ul style="list-style-type: none"> <li>• nose or throat infection (sinusitis or tonsillitis)</li> </ul> <p><b>Signs and symptoms of problems with your muscles:</b></p> <ul style="list-style-type: none"> <li>• muscle weakness, tiredness and/or pain, and/or rapid fatigue of the muscles, in one or more areas of your body.</li> </ul> <p><b>Signs and symptoms of low number of platelets:</b></p> <ul style="list-style-type: none"> <li>• bleeding (e.g. nose or gum bleeding) and/or bruising.</li> </ul> <p><b>Signs and symptoms of infusion (IV) related reactions:</b></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</li> <li>• dizziness or feeling like passing out</li> <li>• fever</li> <li>• back or neck pain</li> <li>• facial swelling</li> </ul> <p><b>Signs and symptoms of encephalitis or meningitis:</b></p> <ul style="list-style-type: none"> <li>• seizures</li> <li>• neck stiffness</li> <li>• headache, fever</li> <li>• chills</li> <li>• vomiting</li> <li>• eye sensitivity to light</li> <li>• confusion and sleepiness.</li> </ul>	<p><b>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.</b></p>

**Most common side effects reported in clinical trials:**

Most common side effects	What to do
<p><b>Reported in patients receiving IMFINZI alone:</b></p> <ul style="list-style-type: none"> <li>• cough</li> <li>• diarrhoea</li> <li>• stomach pain</li> <li>• skin rash or itchiness</li> <li>• fever</li> <li>• swelling of the legs (oedema peripheral)</li> <li>• upper respiratory tract infection</li> <li>• underactive thyroid gland that can cause tiredness or weight gain.</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>
<p><b>Reported in patients receiving IMFINZI in combination with chemotherapy (etoposide and carboplatin or cisplatin):</b></p> <ul style="list-style-type: none"> <li>• low number of white blood cells (Neutropenia and Leukopenia)</li> <li>• low number of red blood cells (Anaemia)</li> </ul>	<p><b>Speak to your doctor if you have any of these side</b></p>

<ul style="list-style-type: none"> <li>• nausea</li> <li>• hair loss</li> <li>• decreased appetite</li> <li>• feeling tired or weak</li> <li>• constipation</li> <li>• low number of platelets (Thrombocytopenia)</li> <li>• vomiting</li> <li>• cough</li> </ul>	<p><b>effects and they worry you.</b></p>
<p><b>Reported in patients receiving IMFINZI in combination with chemotherapy (gemcitabine and cisplatin):</b></p> <ul style="list-style-type: none"> <li>• low number of red blood cells (Anaemia)</li> <li>• low number of white blood cells (Neutropenia and Leukopenia)</li> <li>• low number of platelets (Thrombocytopenia)</li> <li>• diarrhoea</li> <li>• abdominal pain</li> <li>• constipation</li> <li>• nausea</li> <li>• vomiting</li> <li>• feeling tired or weak</li> <li>• fever</li> <li>• abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)</li> <li>• decrease in appetite</li> <li>• skin rash and itchiness</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

**Ask your doctor to answer any questions you may have about side effects.** Tell your doctor or pharmacist if you notice anything else that is 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 and not enough platelets).

Other side effects not listed above may also occur in some people.

#### **After being given Imfinzi**

Do not breast feed for at least 3 months after the last dose.

If you are a woman who could become pregnant, you must use adequate birth control for at least 3 months after your last dose.

#### **Product description**

##### **What it looks like**

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

##### **Ingredients**

**Imfinzi** contains durvalumab as the active ingredient.

Other ingredients include:

- histidine
- histidine hydrochloride monohydrate
- trehalose dihydrate
- polysorbate 80
- water for injection.

##### **How to store Imfinzi**

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.

**Marketed by:**

AstraZeneca Limited  
PO Box 87453, Meadowbank  
Auckland 1742  
Telephone: (09) 306 5650.

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**Date of preparation**

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