

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 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 is used to treat urothelial carcinoma, a type of bladder cancer. It may 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.

Imfinzi is also used to treat a type of lung cancer called Non-Small Cell Lung Cancer (NSCLC). It may 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.

Imfinzi in combination with chemotherapy is also used to treat a type of lung cancer called Extensive-Stage Small Cell Lung Cancer (ES-SCLC). It may 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 in combination with chemotherapy is 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).

When **Imfinzi** is given in combination, it is important that you also read the Consumer Medicine Information (CMI) for the specific chemotherapy you may 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:

- 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

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 worsening cough, shortness of breath, chest pain lung infection (pneumonia or influenza) that may include coughing of phlegm, fever, chills and difficulty breathing. <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 of stomach, yellowing of skin or whites of eyes, drowsiness, dark urine, bleeding or bruising more easily than normal. <p>Problems with your intestines:</p> <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. <p>Problems with your hormone glands:</p> <ul style="list-style-type: none"> inflammation of your hormone glands may include 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, sweet smell to your breath, sweet or metallic taste in your mouth, different odour to your urine or sweat. <p>Problems with your kidney:</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, 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 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 skin or mouth:</p> <ul style="list-style-type: none"> inflammation of the skin or mouth may include rash, itching, skin blistering, 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>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>Problems with your muscles:</p> <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 platelets – may include bleeding (e.g. nose or gum bleeding) and/or bruising. <p>Infusion (IV) related reactions:</p> <ul style="list-style-type: none"> may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or feeling like passing out, fever, back or neck pain, 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 hands, feet or arms. <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 including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation. <p>Inflammation of the joints</p> <ul style="list-style-type: none"> symptoms may include joint pain, swelling, and/or stiffness. 	<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>
<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>

Most common side effects reported in clinical trials:

Most common side effects	What do to
Reported in patients receiving IMFINZI alone: <ul style="list-style-type: none"> • cough • diarrhoea • stomach pain • skin rash or itchiness • fever • swelling of the legs (oedema peripheral) • upper respiratory tract infection • underactive thyroid gland that can cause tiredness or weight gain. 	Speak to your doctor if you have any of these side effects and they worry you.
Reported in patients receiving IMFINZI in combination with chemotherapy (etoposide and carboplatin or cisplatin): <ul style="list-style-type: none"> • low number of white blood cells (Neutropenia and Leukopenia) • low number of red blood cells (Anaemia) • nausea • hair loss • decreased appetite • feeling tired or weak • constipation • low number of platelets (Thrombocytopenia) • vomiting • cough 	Speak to your doctor if you have any of these side effects and they worry you.
Reported in patients receiving IMFINZI in combination with chemotherapy (gemcitabine and cisplatin): <ul style="list-style-type: none"> • low number of red blood cells (Anaemia) • low number of white blood cells (Neutropenia and Leukopenia) • low number of platelets (Thrombocytopenia) • diarrhoea • abdominal pain • constipation • nausea • vomiting • feeling tired or weak • fever • abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased) • decrease in appetite • skin rash and itchiness 	Speak to your doctor if you have any of these side effects and they worry you.

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:

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