

Package leaflet: Information for the patient

Imfinzi® 50 mg/ml concentrate for solution for infusion (durvalumab)

XXXXXXXXXXXX-XXXX

The name of your medicine is Imfinzi 50 mg/ml concentrate for solution for infusion but will be referred to as Imfinzi throughout this leaflet.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Imfinzi is and what it is used for
2. What you need to know before you are given Imfinzi
3. How you are given Imfinzi
4. Possible side effects
5. How to store Imfinzi
6. Contents of the pack and other information

1. What Imfinzi is and what it is used for

Imfinzi contains the active substance durvalumab which is a monoclonal antibody, a type of protein designed to recognise a specific target substance in the body. Imfinzi works by helping your immune system fight your cancer.

Imfinzi is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC) in adults. It is used when your NSCLC:

- has spread within your lung and cannot be removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

It is used in combination with platinum-based chemotherapy prior to surgery (neoadjuvant treatment) and alone after surgery (adjuvant treatment) when your NSCLC:

- has spread within your lung and is able to be removed by surgery.

Imfinzi is used to treat a type of lung cancer called limited-stage small cell lung cancer (LS-SCLC) in adults. It is used when your SCLC:

- has not been removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

Imfinzi in combination with chemotherapy is used to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC) in adults. It is used when your SCLC:

- has spread within your lungs (or to other parts of the body) and
- has not previously been treated.

Imfinzi in combination with chemotherapy is used in adults to treat a type of cancer of the bile ducts (cholangiocarcinoma) and gallbladder that are collectively referred to as biliary tract cancers (BTC). It is used when your BTC:

- has spread within your bile ducts and gallbladder (or to other parts of the body).

Imfinzi in combination with tremelimumab is used to treat a type of liver cancer called advanced or unresectable hepatocellular carcinoma (HCC) in adults. It is used when your HCC:

- cannot be removed by surgery (unresectable), and
- may have spread within your liver or to other parts of the body.

Imfinzi is used to treat a type of uterine cancer (endometrial cancer) that has spread beyond the original tumour or come back (recurred) in adults. It is used in combination with chemotherapy (carboplatin and paclitaxel), followed by:

- Imfinzi alone when your tumour is MMR-deficient, or
- Imfinzi in combination with olaparib when your tumour is MMR-proficient.

A test is used to find out the MMR status of your endometrial cancer.

Imfinzi is used to treat a type of bladder cancer called muscle invasive bladder cancer (MIBC) which is when your bladder cancer has spread into the muscle layer of the bladder but not to other parts of the body. It is used in combination with chemotherapy (neoadjuvant treatment) prior to the surgical removal of your bladder followed by Imfinzi alone after surgery (adjuvant treatment).

If you have any questions about how Imfinzi works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

When Imfinzi is given in combination with other anti-cancer medicines, it is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you are given Imfinzi

You should not be given Imfinzi

- if you are allergic to durvalumab or any of the other ingredients of this medicine (listed in section 6 "Contents of the pack and other information"). Talk to your doctor if you are not sure.

Warnings and precautions

Talk to your doctor before you are given Imfinzi if:

- you have an autoimmune disease (an illness where the body's immune system attacks its own cells);
- you have had an organ transplant;
- you have lung problems or breathing problems;
- you have liver problems.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given Imfinzi.

When you are given Imfinzi, you can have some serious side effects.

If you have any of the following, call or see your doctor straight away. Your doctor may give you other medicines that prevent more severe complications and to help reduce your symptoms. Your doctor may delay the next dose of Imfinzi or stop your treatment with Imfinzi, if you have:

- **inflammation of the lungs:** symptoms may include new or worsening cough, shortness of breath or chest pain;
- **inflammation of the liver:** symptoms may include nausea or vomiting, feeling less hungry, pain on the right side of your stomach, yellowing of skin or whites of eyes, drowsiness, dark urine or bleeding or bruising more easily than normal;
- **inflammation of the intestines:** symptoms may include diarrhoea or more bowel movements than usual, or stools that are black, tarry or sticky with blood or mucus, severe stomach pain or tenderness, hole in the bowel;
- **inflammation of glands:** (especially the thyroid, adrenal, pituitary and pancreas): symptoms may include fast heart rate, extreme tiredness, weight gain or weight loss, dizziness or fainting, hair loss, feeling cold, constipation, headaches that will not go away or unusual headaches, abdominal pain, nausea and vomiting;
- **type 1 diabetes:** symptoms may include high blood sugar, feeling more hungry or thirsty than usual, passing urine more often than usual, 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;
- **inflammation of the kidneys:** symptoms may include decrease in the amount of urine you pass;
- **inflammation of the skin:** symptoms may include rash, itching, skin blistering or ulcers in the mouth or on other moist surfaces;
- **inflammation of the heart muscle:** symptoms may include chest pain, shortness of breath, or irregular heartbeat;
- **inflammation or problems of the muscles:** symptoms may include muscle pain, stiffness or weakness or rapid fatigue of the muscles;
- **inflammation of the spinal cord** (transverse myelitis): 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;
- **infusion-related reactions:** symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or fever;
- **inflammation of the brain** (encephalitis) **or inflammation of the membrane around the spinal cord and brain** (meningitis): symptoms may include seizures, neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness;
- **inflammation of the nerves:** symptoms may include pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome);
- **inflammation of the joints:** signs and symptoms include joint pain, swelling, and/or stiffness (immune-mediated arthritis);
- **inflammation of the eye:** signs and symptoms include eye redness, eye pain, light sensitivity, and/or changes in vision (uveitis);
- **low number of blood platelets:** symptoms may include bleeding (nose or gum bleeding) and/or bruising.
- **low number of red blood cell counts on testing:** symptoms may include shortness of breath, fatigue, pale skin and/or fast heartbeat. When Imfinzi is used in combination with another anti-cancer medicine (olaparib), low red blood cell counts could be a sign of 'pure red cell aplasia' (PRCA), a condition in which no red blood cells are produced, or 'auto-immune haemolytic anaemia' (AIHA), an excessive breakdown of red blood cells.

If you have any of the symptoms listed above, call or see your doctor straight away.

Imfinzi acts on your immune system. It may cause inflammation in parts of your body. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild.

Children and adolescents

Imfinzi should not be used in children and adolescents below 18 years of age as it has not been studied in these patients.

Other medicines and Imfinzi

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription.

Pregnancy

- This medicine is not recommended during pregnancy.
- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are a woman who could become pregnant you must use effective birth control while you are being treated with Imfinzi and for at least 3 months after your last dose.

Breast-feeding

- Tell your doctor if you are breast-feeding.
- Ask your doctor if you can breast-feed during or after treatment with Imfinzi.
- It is not known if Imfinzi passes into human breast milk.

Driving and using machines

Imfinzi is not likely to affect you being able to drive and use machines. However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving or operating machines.

Imfinzi contains Polysorbate 80

This medicine contains 2 mg of polysorbate 80 in each 10 ml of concentrate which is equivalent to 0,2 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How you are given Imfinzi

Imfinzi will be given to you in a hospital or clinic under the supervision of an experienced doctor.

- The recommended dose of Imfinzi is 10 mg per kg of your body weight every 2 weeks, 20 mg per kg every 4 weeks, 1 120 mg every 3 weeks or 1 500 mg every 3 or 4 weeks.
- Your doctor will give you Imfinzi through an infusion (drip) into your vein for about 1 hour.
- Your doctor will decide how many treatments you need.
- Depending on your type of cancer, Imfinzi may be given in combination with other anti-cancer medicines.
- When Imfinzi is given in combination with chemotherapy for your lung cancer or endometrial cancer, you will first be given Imfinzi followed by chemotherapy.

- When Imfinzi is given in combination with tremelimumab for your liver cancer, you will first be given tremelimumab followed by Imfinzi.
- Please refer to the package leaflet 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 get Imfinzi

- Call your doctor straight away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you get Imfinzi, you can have some serious side effects (see section 2).

Talk to your doctor straight away if you get any of the following side effects, that have been reported in clinical studies with patients receiving Imfinzi alone:

Very common (may affect more than 1 in 10 people)

- infections of the upper respiratory tract
- underactive thyroid gland that can cause tiredness or weight gain
- cough
- diarrhoea
- stomach pain
- skin rash or itchiness
- joint pain (arthralgia)
- fever

Common (may affect up to 1 in 10 people)

- serious lung infections (pneumonia)
- flu-like illness
- fungal infection in the mouth
- tooth and mouth soft tissue infections
- overactive thyroid gland that can cause fast heart rate or weight loss
- inflammation of the lungs (pneumonitis)
- hoarse voice (dysphonia)
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- inflammation of the liver that can cause nausea or feeling less hungry (hepatitis)
- night sweats
- inflammation of the skin (dermatitis)
- muscle pain (myalgia)
- abnormal kidney function tests (blood creatinine increased)
- painful urination (dysuria)
- swelling of the legs (oedema peripheral)
- reaction to the infusion of the medicine that can cause fever or flushing of the skin

Uncommon (may affect up to 1 in 100 people)

- low number of blood platelets caused by an immune reaction (immune thrombocytopenia)
- inflammation of thyroid gland (thyroiditis)
- decreased secretion of hormones produced by the adrenal glands that can cause tiredness
- underactive pituitary gland; inflammation of pituitary gland
- a condition leading to high blood sugar levels (type 1 diabetes mellitus)
- a condition in which the muscles become weak and there is a rapid fatigue of the muscles (myasthenia gravis)
- inflammation of the brain (encephalitis)
- inflammation of the heart (myocarditis)
- scarring of lung tissue
- inflammation of the gut or intestine (colitis)
- inflammation of the pancreas (pancreatitis)
- red, itchy, dry, scaly patches of thickened skin (psoriasis)
- blistering of the skin (pemphigoid)
- inflammation of the muscle (myositis)
- inflammation of the joints (immune-mediated arthritis)
- inflammation of the kidneys (nephritis) that can decrease the amount of your urine
- inflammation of the bladder (cystitis). Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen

Rare (may affect up to 1 in 1 000 people) diabetes insipidus

- inflammation of the eye (uveitis)
- inflammation of the membrane around the spinal cord and brain (meningitis)
- coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- lack or reduction of pancreatic enzymes and hormones required for digestion (pancreatic failure)
- inflammation of the muscles and vessels (polymyositis)
- inflammation of the muscles causing pain or stiffness (polymyalgia rheumatica)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

Other side effects that have been reported with frequency not known (cannot be estimated from the available data)

- inflammation of the nerves: (Guillain-Barré syndrome)
- inflammation of part of the spinal cord (transverse myelitis)

The following additional side effects to receiving Imfinzi alone have been reported in clinical studies in patients taking Imfinzi in combination with chemotherapy (the frequency and severity of side effects may vary depending on chemotherapeutic agents received):

Very common (may affect more than 1 in 10 people)

- low number of white blood cells
- low number of red blood cells
- low number of blood platelets
- nausea; vomiting; constipation
- hair loss
- feeling less hungry
- feeling tired or weak
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs (neuropathy peripheral)
- lack of energy; general feeling of discomfort or illness

The following information is intended for healthcare professionals only. Preparation and administration of the infusion

- Parenteral medicinal products should be inspected visually for particulate matter and discoloration prior to administration. The concentrate is a clear to opalescent, colourless to slightly yellow solution, free from visible particles. Discard the vial if the solution is cloudy, discoloured or visible particles are observed.
- Do not shake the vial.
- Withdraw the required volume of concentrate from the vial(s) and transfer into an intravenous bag containing sodium chloride 9 mg/ml (0.9%) solution for injection, or glucose 50 mg/ml (5%) solution for injection, to prepare a diluted solution with a final concentration ranging from 1 to 15 mg/ml. Mix diluted solution by gentle inversion.
- The medicinal product, once diluted, should be used immediately. The diluted solution must not be frozen. Chemical and physical in-use stability has been demonstrated for up to 30 days at 2 °C to 8 °C and for up to 24 hours at room temperature (up to 25 °C) from the time of preparation.
- From a microbiological point of view, the prepared solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer 24 hours at 2 °C to 8 °C or 12 hours at room temperature (up to 25 °C), unless dilution has taken place in controlled and validated aseptic conditions.
- If refrigerated, intravenous bags must be allowed to come to room temperature prior to use. Administer the infusion solution intravenously over 1 hour using a sterile, low-protein binding 0.2 or 0.22 micron in-line filter.
- Do not co-administer other medicinal products through the same infusion line.
- Imfinzi is single-dose. Discard any unused portion left in the vial.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.



Common (may affect up to 1 in 10 people)

- low number of white blood cells with signs of fever (febrile neutropenia)
- inflammation of the mouth or lips (stomatitis)

Uncommon (may affect up to 1 in 100 people)

- low number of red blood cells, white blood cells, and platelets (pancytopenia)

The following additional side effects to receiving Imfinzi alone have been reported in clinical trials in patients taking Imfinzi in combination with tremelimumab:

Common (may affect up to 1 in 10 people)

- abnormal pancreas function tests

Rare (may affect up to 1 in 1 000 people)

- coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

Other side effects that have been reported with frequency not known (cannot be estimated from the available data)

- hole in the bowel (intestinal perforation)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

The following additional side effects to receiving Imfinzi alone have been reported in clinical studies in patients taking Imfinzi in combination with platinum-based chemotherapy followed by Imfinzi with olaparib:

Very common (may affect more than 1 in 10 people)

- low number of red blood cells
- low number of white blood cells (neutropenia and leukopenia)
- low number of blood platelets
- feeling less hungry
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs (neuropathy peripheral)
- nausea, vomiting; constipation
- dizziness
- headache
- changes in taste of foods (dysgeusia)
- shortness of breath (dyspnoea)
- inflammation of the mouth or lips (stomatitis)
- hair loss
- feeling tired or weak

Common (may affect up to 1 in 10 people)

- low number of white blood cells with fever (febrile neutropenia)
- low levels of lymphocytes, a type of white blood cell
- allergic reactions
- indigestion or heartburn (dyspepsia)
- blood clot in a deep vein, usually in the leg (venous thrombosis) that may cause symptoms such as pain or swelling of the legs
- failure to produce red blood cells (pure red cell aplasia) that may cause symptoms such as shortness of breath, fatigue, pale skin or fast heart beat

Uncommon (may affect up to 1 in 100 people)

- low number of red blood cells, white blood cells, and platelets (pancytopenia)

Talk to your doctor straight away if you get any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imfinzi

Imfinzi will be given to you in a hospital or clinic and the healthcare professional will be responsible for its storage. The storage details are as follows:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C).

Do not freeze.

Store in the original package in order to protect from light.

Do not use if this medicine is cloudy, discoloured or contains visible particles.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not store any unused portion of the infusion solution for re-use. Any unused medicine or waste material should be disposed of in accordance with local requirements.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Imfinzi contains**

The active substance is durvalumab.

Each ml of concentrate for solution for infusion contains 50 mg of durvalumab.

Please remove the cap from the vial and either 500 mg of durvalumab in 10 ml of concentrate.

The other ingredients are: histidine, histidine hydrochloride monohydrate, trehalose dihydrate, polysorbate 80, water for injections.

What Imfinzi looks like and contents of the pack

Imfinzi concentrate for solution for infusion (sterile concentrate) is a preservative-free, clear to opalescent, colourless to slightly yellow solution, free from visible particles.

It is available in packs containing 1 glass vial of 10 ml of concentrate.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

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**Imfinzi 50 mg/ml concentrate for solution for infusion
PL 45985/0990**

POM

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