

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 0.1 to 10 mg/ml. Mix diluted solution by gentle inversion.

- Use the medicinal product immediately once diluted. The diluted solution must not be frozen. If not used immediately, the total time from vial puncture to start of the administration should not exceed 24 hours at 2 °C to 8 °C or 12 hours at room temperature (up to 25 °C). 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.

- IMJUDO is a 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.

ONC 25 0022

Information for the patient

IMJUDO® 20 mg/ml concentrate for infusion

tremelimumab

Package leaflet: Information for the patient

IMJUDO® 20 mg/ml concentrate for infusion

tremelimumab

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Package leaflet: Information for the patient

IMJUDO® 20 mg/ml concentrate for solution for infusion tremelimumab

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- What IMJUDO is and what it is used for
- What you need to know before you are given IMJUDO
- How you are given IMJUDO
- Possible side effects
- How to store IMJUDO
- Contents of the pack and other information

1. What IMJUDO is and what it is used for

IMJUDO is an anti-cancer medicine. It contains the active substance tremelimumab, which is a type of medicine called a *monoclonal antibody*. This medicine is designed to recognise a specific target substance in the body. IMJUDO works by helping your immune system fight your cancer.

IMJUDO in combination with durvalumab is used to treat a type of liver cancer, called advanced or unresectable hepatocellular carcinoma (HCC). 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.

As IMJUDO will be 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 IMJUDO

You should not be given IMJUDO if you are allergic to tremelimumab or any of the other ingredients of this medicine (listed in section 6). Talk to your doctor if you are not sure.

Warnings and precautions

Talk to your doctor before you are given IMJUDO 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 or breathing problems
- you have liver problems.

Talk to your doctor before you are given IMJUDO if any of these could apply to you.

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

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 IMJUDO or stop your treatment with IMJUDO. **Talk to your doctor straight away** if you get any of the following side effects:

- new or worsening cough; shortness of breath; chest pain (may be signs of **lung inflammation**)
- feeling sick (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 may be signs of **liver inflammation**)
- diarrhoea or more bowel movements than usual; stools that are black, tarry or sticky with blood or mucus; severe stomach pain or tenderness (may be signs of **bowel inflammation**, or a hole in the bowel)
- 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 (may be signs of **glands** being inflamed, especially the thyroid, adrenal, pituitary or pancreas)
- feeling more hungry or thirsty than usual; passing urine more often than usual; high blood sugar; fast and deep breathing; confusion; a sweet smell to your breath; a sweet or metallic taste in your mouth or a different odour to your urine or sweat (may be signs of **diabetes**)
- decrease in the amount of urine you pass (may be sign of **kidney inflammation**)
- rash; itching; skin blistering or ulcers in the mouth or on other moist surfaces (may be signs of **skin inflammation**)
- chest pain; shortness of breath; irregular heartbeat (may be signs of **heart muscle inflammation**)
- muscle pain or stiffness or weakness or rapid tiring of the muscles (may be signs of inflammation or other problems of the **muscles**)
- chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or fever (may be signs of **infusion-related reactions**)
- seizures; neck stiffness; headache; fever, chills; vomiting; eye sensitivity to light; confusion and sleepiness (may be signs of inflammation of the **brain** or the membrane around the brain and **spinal cord**)
- 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
- pain; weakness and paralysis in the hands, feet or arms (may be signs of inflammation of the **nerves**, Guillain-Barré syndrome)
- joint pain, swelling, and/or stiffness (may be signs of inflammation of the **joints**, immune-mediated arthritis)
- eye redness, eye pain, light sensitivity, and/or changes in vision (may be signs and symptoms of inflammation of the **eye**, uveitis)
- bleeding (from the nose or gums) and/or bruising (may be signs of **low blood platelets**).

Talk to your doctor straight away if you have any of the symptoms listed above.

Children and adolescents

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

Other medicines and IMJUDO

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 and fertility

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 contraception while you are being treated with IMJUDO and for at least 3 months after your last dose.

Breast-feeding

Tell your doctor if you are breast-feeding. It is not known if IMJUDO passes into human breast milk. You may be advised to not breast-feed during treatment and for at least 3 months after your last dose.

Driving and using machines

IMJUDO is not likely to affect your driving or use of machines. However, if you have side effects that affect your ability to concentrate and react, be careful when driving or operating machines.

IMJUDO has a low sodium content

IMJUDO contains less than 1 mmol sodium (23 mg) in each dose, that is to say essentially sodium-free.

IMJUDO contains polysorbate

This medicine contains 0.3 mg of polysorbate 80 in a 1.25 ml vial, or 3 mg of polysorbate 80 in a 15 ml vial, 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 IMJUDO

IMJUDO will be given to you in a hospital or clinic under the supervision of an experienced doctor. Your doctor will give you IMJUDO as a drip into your vein (infusion) lasting about an hour.

It is given in combination with durvalumab for liver cancer.

The recommended dose

- If you weigh 40 kg or more, the dose is 300 mg as a one-time single dose.
- If you weigh less than 40 kg, the dose will be 4 mg per kg of your body weight.

When IMJUDO is given in combination with durvalumab for your liver cancer, you will be given IMJUDO first, then durvalumab.

If you miss an appointment

It is very important that you do not miss a dose of this medicine. If you miss an appointment, **call your doctor straight away** to reschedule your appointment.

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 IMJUDO, you can have some serious side effects. **See section 2** for a detailed list of these.

Talk to your doctor straight away if you get any of the following side effects that have been reported in a clinical study with patients receiving IMJUDO in combination with durvalumab.

The following side effects have been reported in clinical trials in patients taking IMJUDO in combination with durvalumab:

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

- underactive thyroid gland that can cause tiredness or weight gain
 - cough
 - diarrhoea
 - stomach pain
- abnormal liver tests (aspartate aminotransferase increased; alanine aminotransferase increased)
- skin rash
- itchiness
- fever
- swelling of legs (oedema peripheral)

Common (may affect up to 1 in 10 people)

- infections of the upper respiratory tract
- lung infection (pneumonia)
- flu-like illness
- tooth and mouth soft tissue infections
- overactive thyroid gland that can cause fast heart rate or weight loss
- inflammation of the thyroid gland (thyroiditis)
- decreased secretion of hormones produced by the adrenal glands that can cause tiredness
 - inflammation of the lungs (pneumonitis)
 - abnormal pancreas function tests
 - inflammation of the gut or intestine (colitis)
 - inflammation of the pancreas (pancreatitis)
 - inflammation of the liver (hepatitis)
 - inflammation of the skin
 - night sweats
 - muscle pain (myalgia)
 - abnormal kidney function test (blood creatinine increased)
 - painful urination (dysuria)
 - reaction to the infusion of the medicine that can cause fever or flushing

Uncommon (may affect up to 1 in 100 people)

- fungal infection in the mouth
- low number of platelets with signs of excessive bleeding and bruising (immune thrombocytopenia)
- underactive pituitary gland; inflammation of pituitary gland
- 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 membrane around the spinal cord and brain (meningitis)
- inflammation of the heart (myocarditis)
- hoarse voice (dysphonia)
- scarring of lung tissue
- blistering of the skin
- inflammation of the muscles (myositis)
- inflammation of the muscles and vessels
- inflammation of the kidneys (nephritis) that can decrease the amount of your urine
- inflammation of the joints (immune-mediated arthritis)
- inflammation of the muscles causing pain or stiffness (polymyalgia rheumatica)

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

- diabetes insipidus
- inflammation of the eye (uveitis)
- inflammation of the brain (encephalitis)
- inflammation of the nerves (Guillain-Barré syndrome)
- hole in the bowel (intestinal perforation)
- coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- 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.

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

- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)
- inflammation of part of the spinal cord (transverse myelitis)

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 at 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 IMJUDO

IMJUDO will be given to you in a hospital or clinic and the healthcare professional will be responsible for its storage.

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 - 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.

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.

6. Contents of the pack and other information

What IMJUDO contains

The active substance is tremelimumab.

Each ml of concentrate for solution for infusion contains 20 mg of tremelimumab.

One vial contains either 300 mg of tremelimumab in 15 ml of concentrate or 25 mg of tremelimumab in 1.25 ml of concentrate.

The other ingredients are: histidine, histidine hydrochloride monohydrate, trehalose dihydrate, disodium edetate dihydrate (see section 2 "IMJUDO has a low sodium content"), polysorbate 80 (E 433) and water for injections.

What IMJUDO looks like and contents of the pack

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

It is available in packs containing either 1 glass vial of 1.25 ml of concentrate or 1 glass vial of 15 ml of concentrate.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

AstraZeneca UK Limited,
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Manufacturer

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This leaflet was last revised in 05/2025.

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ONC 25 0022

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000

Please be ready to give the following information:

Product name **Reference number**

IMJUDO 20mg/mL

solution for infusion

17901/0368

This is a service provided by the Royal National Institute of the Blind.

AstraZeneca

Text area



