

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

IMJUDO is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using IMJUDO?

IMJUDO contains the active ingredient tremelimumab. IMJUDO is used in combination with durvalumab to treat a type of liver cancer in adults, called unresectable hepatocellular carcinoma (uHCC).
For more information, see Section [1. Why am I using IMJUDO?](#) in the full CMI.

2. What should I know before I use IMJUDO?

Do not use if you have ever had an allergic reaction to IMJUDO or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section [2. What should I know before I use IMJUDO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMJUDO and affect how it works.
A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use IMJUDO?

- IMJUDO will be given to you through an infusion into your vein for about 1 hour.
 - IMJUDO will be given in combination with durvalumab as a one-time-single dose. You will first be given IMJUDO followed by durvalumab.
- More instructions can be found in Section [4. How do I use IMJUDO?](#) in the full CMI.

5. What should I know while using IMJUDO?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using IMJUDO • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not miss a dose of IMJUDO
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how IMJUDO affects you

For more information, see Section [5. What should I know while using IMJUDO?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may be serious and therefore may need immediate medical attention or hospitalisation. See Section [6. Are there any side effects?](#) in the full CMI and, if you need to, ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.
For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

IMJUDO®

Active ingredient(s): *tremelimumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMJUDO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IMJUDO.**

Where to find information in this leaflet:

1. [Why am I using IMJUDO?](#)
2. [What should I know before I use IMJUDO?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use IMJUDO?](#)
5. [What should I know while using IMJUDO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using IMJUDO?

IMJUDO contains the active ingredient tremelimumab. IMJUDO is medicine to treat cancer. It belongs to the monoclonal antibody class of anticancer medicines. IMJUDO works by helping your immune system fight your cancer.

IMJUDO in combination with durvalumab is used to treat a type of liver cancer in adults, called unresectable hepatocellular carcinoma (uHCC). It is used when your uHCC:

- cannot be removed by surgery (unresectable) and
- may have spread within your liver 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 consumer leaflet for these other medicines. If you have any questions about these medicines, ask your doctor.

2. What should I know before I use IMJUDO?

Warnings

Do not use IMJUDO if:

- you are allergic to tremelimumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have an autoimmune disease (a condition where the body attacks its own cells) like Crohn's disease, ulcerative colitis or lupus. If you already have an autoimmune disease, your risk of immune-mediated side effects may be higher with immune checkpoint inhibitor medicines (such as IMJUDO) as they may cause inflammation in parts of your body. You may also experience more frequent flares of your autoimmune disease, which in the majority of cases are mild.
- have had an organ transplant;
- have lung or breathing problems;
- have liver problems;
- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

IMJUDO can harm your unborn baby.

If you are able to 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 IMJUDO.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if IMJUDO passes into your breast milk.

Do not breastfeed during treatment and for at least 3 months after the last dose of IMJUDO.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IMJUDO.

4. How do I use IMJUDO?

How much and when to take IMJUDO

- IMJUDO will be given to you through an infusion (drip) into your vein (IV) for about 1 hour.
- IMJUDO will be given in combination with durvalumab as a one-time-single dose. You will first be given IMJUDO followed by durvalumab.

If you miss an appointment to get IMJUDO

Call your doctor right 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.

5. What should I know while using IMJUDO?

Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are using IMJUDO.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IMJUDO affects you.

IMJUDO is unlikely to affect the ability to drive and use machines.

However, if you experience adverse reactions affecting your ability to concentrate and react, you should use caution when driving or operating machinery.

Looking after your medicine

IMJUDO will be given to you in a healthcare facility and the healthcare professionals caring for you will be responsible for storing this medicine.

- Store in a refrigerator at 2°C to 8°C in the original package to protect from light.
- Do not freeze.
- Do not shake

Getting rid of any unwanted medicine

Unused medicine or waste material will be discarded by your healthcare professional.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When you are given IMJUDO in combination with durvalumab, you can have some side effects. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Most common side effects

Most common side effects	What to do
• Underactive thyroid gland that can cause tiredness or weight gain • Stomach pain • Diarrhoea • Swelling of legs • Fever • Cough • Itchiness • Skin rash	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Problems with your lungs: • lung inflammation that may include new or worsening cough, shortness of breath, chest pain Problems with your liver: • 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 or bleeding or bruising more easily than normal. Problems with your intestines: • inflammation of the intestines that may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucous, severe stomach pain or tenderness; may lead to a hole in intestinal wall. Problems with some of your hormone glands: • inflammation of your hormone glands (especially the thyroid, adrenals, pituitary and pancreas) that 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	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.

Serious side effects	What to do
voice, urinating more often than usual, nausea or vomiting, stomach area (abdomen) pain, changes in mood or behaviour, such as decreased sex drive, irritability or forgetfulness, 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. Problems with your kidney - inflammation of your kidney that may include changes in the amount or colour of your urine, swelling in your ankles or loss of appetite Problems with your skin or mouth: - inflammation of the skin and mouth that may include rash, itching, skin blistering or ulcers in mouth or other mucous membranes. Problems with your heart: - inflammation of your heart may include chest pain, shortness of breath or irregular heartbeat. Problems with your muscles: - inflammation or problems of the muscles that may include muscle weakness, tiredness and/or pain, and/or rapid fatigue of the muscles, in one or more areas of your body. Problems with your brain: - inflammation of the brain that may include seizures, headache, fever, chills, vomiting, confusion and sleepiness. Problems with your platelets: - low number of platelets that may include bleeding (e.g. nose or gum bleeding) and/or bruising. Problems with your nerves: - inflammation of the nerves that may include pain, weakness and paralysis in the hands, feet or arms.	

Serious side effects	What to do
Problems with your joints: - inflammation of the joints that may include joint pain, swelling, and/or stiffness. Infusion-related reactions: - may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling like passing out, back or neck pain or facial swelling.	
Problems with your eyes inflammation of the eye that may include eye redness, eye pain, light sensitivity, and/or changes in vision.	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.

Immune checkpoint inhibitor class effects

There have been cases of the following serious side effects reported during treatment with other medicines in this class which may also occur during treatment with IMJUDO:

- decreased ability of the pancreas to make digestive enzymes, which may result in symptoms such as diarrhoea with loose and oily stools, weight loss, metabolic bone disease, and vitamin or mineral deficiencies (known as exocrine pancreatic insufficiency).
- decreased production of blood cells, which may result in symptoms such as weakness, shortness of breath, dizziness, fast or irregular heartbeat, frequent infections, unexplained or easy bruising, or bleeding from gums or other tissues (known as aplastic anaemia).
- a condition where the immune system makes too many infection-fighting cells which may result in symptoms such as an enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities and heart problems (known as haemophagocytic lymphohistiocytosis).
- coeliac disease which may result in symptoms such as stomach pain, diarrhoea and bloating after consuming gluten-containing foods).

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.

Tell your doctor or pharmacist if you notice anything else that may be 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 abnormal pancreas and liver tests).

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What IMJUDO contains

Active ingredient (main ingredient)	tremelimumab
Other ingredients (inactive ingredients)	• histidine • histidine hydrochloride monohydrate • trehalose dihydrate • disodium edetate • polysorbate 80 • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What IMJUDO looks like

IMJUDO concentrate for solution for infusion is a clear to slightly opalescent, colourless to slightly yellow solution, free from or practically free from visible particles.

Australian Registration Number(s):

- IMJUDO 25 mg (25 mg/1.25 mL) vial for intravenous infusion – AUST R 387299
- IMJUDO 300 mg (300 mg/15 mL) vial for intravenous infusion – AUST R 387300

Who distributes IMJUDO

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

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VV-RIM-04946025 v5.0

This leaflet was prepared on 22 July 2025.