

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

IMJUDO®

tremelimumab for injection

This patient medication information is written for the person who will be taking **IMJUDO**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **IMJUDO**, talk to a healthcare professional.

Serious warnings and precautions box

IMJUDO in combination with durvalumab can cause serious side effects which can lead to death. These serious side effects may include: inflammation of the intestines (enterocolitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (Stevens-Johnson syndrome); inflammation of hormone glands that may affect how these glands work; inflammation of the lung tissue (pneumonitis or interstitial lung disease); inflammation of the heart muscle (myocarditis); inflammation of the brain (encephalitis); neuromuscular disease that leads to skeletal muscle weakness (myasthenia gravis). Please see **Possible side effects from using IMJUDO**.

What IMJUDO is used for:

IMJUDO in combination with durvalumab is used to treat a type of liver cancer, called hepatocellular carcinoma (HCC). IMJUDO is used with another drug, durvalumab when your liver cancer:

- cannot be removed by surgery (unresectable) and requires medication,
- may have spread within your liver or to other parts of the body, and
- you have not received other medicines to treat your liver cancer.

If you are given IMJUDO in combination with durvalumab, it is important that you also read the PATIENT MEDICATION INFORMATION for both medications.

How IMJUDO works:

Tremelimumab is a monoclonal antibody, which is a type of protein designed to recognise and attach to a specific target substance in the body. IMJUDO together with durvalumab are medicines that may treat your liver cancer by working with your immune system to attack the cancer cells.

IMJUDO will only be prescribed to you by a doctor with experience in the use of medicines for cancer.

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

The ingredients in IMJUDO are:

Medicinal ingredient(s): tremelimumab

Non-medicinal ingredients: disodium edetate dihydrate, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, α,α -Trehalose dihydrate, and water for injection

IMJUDO comes in the following dosage form(s):

A solution in single-use glass vials containing either 1.25 mL or 15 mL of 20 mg/mL tremelimumab.

After further dilution and preparation, IMJUDO is administered as an intravenous infusion.

Do not use IMJUDO if:

- You are allergic to tremelimumab or any other ingredients in IMJUDO.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IMJUDO. Talk about any health conditions or problems you may have, including if you:

- Have had an organ transplant.
- Have lung or breathing problems.
- Have liver problems.
- Have immune system problems such as Crohn's disease, ulcerative colitis, or lupus.
- Have problems with hormone producing glands such as your thyroid, pituitary, adrenal glands, or pancreas.
- Have diabetes.

Other warnings you should know about:Pediatrics

- IMJUDO has not been authorised for use in children or adolescents. IMJUDO should not be given to children or adolescents. This is because the effects of IMJUDO in people younger than 18 years of age are not known.

Pregnancy

- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor before taking this medicine.
- If you are a woman who could 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.

Breastfeeding

- If you are breastfeeding or plan to breastfeed, tell your doctor.
- Do not breastfeed during treatment and for at least 3 months after the last dose of IMJUDO. It is not known if IMJUDO passes into your breast milk.

Driving and using machines

If you experience side effects affecting your ability to concentrate and react, do not drive, or use machines until you feel better.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IMJUDO:

- No drug-drug interactions are expected with IMJUDO.

How to take IMJUDO:

- IMJUDO will be given to you in a hospital or clinic under the supervision of an experienced healthcare professional.
- Your healthcare professional will give you IMJUDO through an intravenous infusion into your vein for about 60 minutes.

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

Usual dose:

The recommended dose of IMJUDO is 300 mg as a single dose, followed by durvalumab 1500 mg at Day 1 of Cycle 1. Continue durvalumab 1500 mg on its own every 4 weeks.

If you have a body weight of 30 kg or less, you must receive weight-based dosing, equivalent to IMJUDO 4 mg/kg as a single dose, followed by durvalumab 20 mg/kg at Day 1 of Cycle 1. Continue durvalumab 20 mg/kg on its own every 4 weeks.

Overdose:

If you think you, or a person you are caring for, have taken too much IMJUDO, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

It is very important that you keep all your appointments. If you miss an appointment, call your doctor as soon as possible to discuss next steps.

Possible side effects from using IMJUDO:

These are not all the possible side effects you may have when taking IMJUDO. If you experience any side effects not listed here, tell your healthcare professional.

Very common side effects ($\geq 10\%$):

- Underactive thyroid gland that can cause tiredness or weight gain
- Stomach pain
- Diarrhea
- Abnormal pancreas test
- Swelling of legs
- Fever
- Abnormal liver tests
- Cough
- Itchiness
- Skin rash
- Feeling tired

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hormone gland problems (especially the thyroid, adrenals, pituitary and pancreas): 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, irritability, or forgetfulness, fast and deep breathing, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth, a different odour to your urine or sweat, increased frequency of urination (peeing) or feeling unusually thirsty.		✓	
Skin problems: rash, itching, skin blistering.		✓	
COMMON			
Liver problems (hepatitis): yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea coloured), bleeding or bruising more easily than normal, feeling less hungry than usual.		✓	
Lung inflammation (pneumonitis): new or worsening cough, shortness of breath, chest pain.		✓	
Muscle problems: muscle weakness, tiredness and/or pain, rapid fatigue of the muscles in one or more areas of your body.		✓	
Pneumonia (infection in the lungs): cough with or without mucus, fever, chills, shortness of breath, chest pain including difficult and painful breathing.		✓	
Severe infusion reactions: chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling like passing out, back or neck pain, facial swelling.		✓	
Intestinal problems (colitis) that can lead to tears or holes in your intestine: diarrhea or more bowel movements than usual, stools that are black, tarry, sticky, or have blood or mucus, severe stomach area (abdomen) pain.		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Kidney problems, including inflammation (nephritis) and kidney failure: decrease in the amount of urine, blood in your urine, swelling in your ankles, loss of appetite.		✓	
Problems in other organs: changes in eyesight, blurry vision, double vision, cloudy vision or other vision problems including temporary loss of vision, severe or persistent muscle or joint pains, chest pain, shortness of breath.		✓	
Inflammation of the heart: chest pain, shortness of breath or irregular heartbeat.		✓	
RARE			
Low number of platelets: bleeding (e.g., nose or gum bleeding) and/or bruising.		✓	
Inflammation of the brain: seizures, headache, fever, chills, vomiting, confusion, and sleepiness.		✓	
UNKNOWN			
Inflammation of the nerves: signs and symptoms may include pain; weakness and paralysis in the hands, feet, or arms.		✓	
Inflammation of the joints: signs and symptoms may include joint pain, swelling, and/or stiffness.		✓	
Inflammation of the eye: signs and symptoms may include eye redness, eye pain, light sensitivity, and/or changes in vision.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage (for Healthcare Professional):

IMJUDO should not be used after the expiry date, which is stated on the label and carton.

IMJUDO should be stored in a refrigerator (2° to 8°C) in the original package in order to protect from light. Do not freeze or shake. Any unused medicine or waste material should be disposed of in accordance with local requirements.

Keep out of reach and sight of children.

If you want more information about IMJUDO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.astrazeneca.ca; or by calling 1-800-668-6000.

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4

Date of Authorization: 2025-06-20

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