

MEDICATION GUIDE
IMJUDO® (im-JEW-doh)
(tremelimumab-actl)
injection

What is the most important information I should know about IMJUDO?

IMJUDO is a medicine that may treat certain cancers by working with your immune system.

IMJUDO in combination with durvalumab can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Lung problems.

- cough
- shortness of breath
- chest pain

Intestinal problems.

- diarrhea (loose stools) or more frequent bowel movements than usual
- severe stomach-area (abdomen) pain or tenderness
- stools that are black, tarry, sticky, or have blood or mucus

Liver problems.

- yellowing of your skin or the whites of your eyes
- dark urine (tea colored)
- severe nausea or vomiting
- bleeding or bruising more easily than normal
- pain on the right side of your stomach-area (abdomen)

Hormone gland problems.

- headaches that will not go away or unusual headaches
- urinating more often than usual
- eye sensitivity to light
- hair loss
- eye problems
- feeling cold
- rapid heartbeat
- constipation
- increase sweating
- your voice gets deeper
- extreme tiredness
- dizziness or fainting
- weight gain or weight loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- feeling more hungry or thirsty than usual

Kidney problems.

- decrease in your amount of urine
- swelling of your ankles
- blood in your urine
- loss of appetite

Skin problems.

- rash
- painful sores or ulcers in mouth or nose, throat, or genital area
- itching
- fever or flu-like symptoms
- skin blistering or peeling
- swollen lymph nodes

Pancreas problems.

- pain in your upper stomach-area (abdomen)
- loss of appetite
- severe nausea or vomiting

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with IMJUDO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeats, shortness of breath or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems
- tingling, numbness or weakness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight
- persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling
- low red blood cells, bruising

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back or neck pain

Getting medical treatment right away may help keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during your treatment with IMJUDO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with IMJUDO, if you have severe side effects.

What is IMJUDO?

IMJUDO is a prescription medicine used to treat adults with:

- **a type of liver cancer** called unresectable hepatocellular carcinoma (uHCC). IMJUDO may be used in combination with durvalumab when your uHCC cannot be removed by surgery.
- **a type of lung cancer** called non-small cell lung cancer (NSCLC). IMJUDO may be used in combination with durvalumab and chemotherapy that contains platinum when your NSCLC:
 - has spread to other parts of your body (metastatic), **and**
 - your tumor does not have an abnormal “EGFR” or “ALK” gene.

It is not known if IMJUDO is safe and effective in children.

Before you receive IMJUDO, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. IMJUDO can harm your unborn baby.

Females who are able to become pregnant

- Your healthcare provider should do a pregnancy test before you start treatment with IMJUDO.
- You should use an effective method of birth control during your treatment and for 3 months after your last dose of IMJUDO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with IMJUDO.
- are breastfeeding or plan to breastfeed. It is not known if IMJUDO passes into your breast milk. Do not breastfeed during treatment and for 3 months after your last dose of IMJUDO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive IMJUDO?

- Your healthcare provider will determine your treatment schedule and cycles of treatment.
- Your healthcare provider will give you IMJUDO into your vein through an intravenous (IV) line over 60 minutes.
- **For the treatment of uHCC:**
 - On the same day you receive IMJUDO, you will receive durvalumab through an intravenous (IV) line over 60 minutes.
 - IMJUDO is given to you as a single dose.
 - You will then receive durvalumab every 4 weeks
- **For the treatment of NSCLC:**
 - On the same day you receive IMJUDO, you will receive durvalumab followed by platinum-containing chemotherapy. You will receive combination chemotherapy every 3 weeks for four cycles (Cycle 1 to 4).
 - You will then receive durvalumab for one cycle (Cycle 5), and then IMJUDO in combination with durvalumab for one cycle only (Cycle 6).
 - You will then receive durvalumab every 4 weeks.
 - Your healthcare provider will decide if you will also receive additional chemotherapy with each cycle.
- Your healthcare provider will test your blood to check you for certain side effects.
- If you miss your appointment, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of IMJUDO?

IMJUDO can cause serious side effects, including:

See “What is the most important information I should know about IMJUDO?”

The most common side effects of IMJUDO when used in combination with durvalumab in adults with uHCC include:

- rash
- diarrhea
- feeling tired
- itchiness
- muscle or bone pain
- stomach area (abdominal) pain

The most common side effects of IMJUDO when used in combination with durvalumab and platinum-containing chemotherapy in adults with metastatic NSCLC include:

- nausea
- feeling tired or weak
- muscle or bone pain
- decreased appetite
- rash
- diarrhea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of IMJUDO. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMJUDO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about IMJUDO, talk with your healthcare provider. You can ask your healthcare provider for information about IMJUDO that is written for health professionals.

What are the ingredients in IMJUDO?

Active ingredient: tremelimumab-actl

Inactive ingredients: edetate disodium, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, trehalose, and Water for Injection, USP.

Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

Manufactured by: AstraZeneca AB, Södertälje, Sweden SE-15185

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For more information, call 1-800-236-9933 or go to www.IMJUDO.com

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