

IMJUDO[®]

(tremelimumab)

PATIENT MEDICATION GUIDE

1. WHAT IMJUDO IS AND WHAT IT IS USED FOR

IMJUDO is a medicine used to treat cancer in adults. It contains the active substance tremelimumab which belongs to the monoclonal antibody class of anticancer medicines. IMJUDO works by helping your immune system to fight cancer.

IMJUDO in combination with durvalumab is used to treat a type of liver cancer, called unresectable (cannot be removed by surgery) hepatocellular carcinoma (uHCC), in patients who have not received prior oral or injectable medicines for it.

As IMJUDO will be given in combination with other anti-cancer medicines, it is important that you ask your doctor if you have any questions about these medicines.

2. WARNINGS AND PRECAUTIONS

Tell your doctor before you are given IMJUDO if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus.
- have had an organ transplant.
- have lung or breathing problems.
- have liver problems.
- are pregnant or plan to become pregnant. (IMJUDO can harm your unborn baby. If you can 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.)
- are breastfeeding or plan 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.)

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.


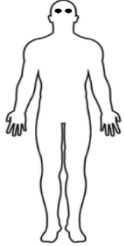


Driving and using machines





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

If you experience any adverse reactions affecting your ability to concentrate and react, you should exercise caution when driving or operating machinery.

3. IMPORTANT SIGNS AND SYMPTOMS TO LOOK OUT FOR

In some patients, Imjudo in combination with durvalumab can cause the immune system to attack normal organs and tissues and affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death if left untreated. If you have any of the following, call or see your doctor right away. Do not attempt to treat any of the symptoms without talking to your doctor first.

INFLAMMATION OF THE BRAIN		INFLAMMATION OF THE EYES	
	<ul style="list-style-type: none"> • Seizures • Headache • Fever • Chills • Vomiting • Confusion • Sleepiness 		<ul style="list-style-type: none"> • Eye redness • Eye pain • Light sensitivity • Changes in vision • Small shapes moving across your field of vision (floaters)
INFLAMMATION OF THE SKIN OR MOUTH		INFLAMMATION OF THE HEART	
	<ul style="list-style-type: none"> • Rash • Itching • Skin blistering • Ulcers in mouth or other mucous membranes 		<ul style="list-style-type: none"> • Chest pain • Shortness of breath • Irregular heartbeat • Tiredness • Heart palpitations

INFLAMMATION OF THE LUNGS		INFLAMMATION OF THE INTESTINES	
	<ul style="list-style-type: none"> • New or worsening cough • Shortness of breath or chest pain 		<ul style="list-style-type: none"> • Diarrhoea • More bowel movements than usual • Black, tarry, sticky stools • Stools with blood or mucus • Severe stomach pain or tenderness
INFLAMMATION OF THE KIDNEYS		INFLAMMATION OF THE LIVER	
	<ul style="list-style-type: none"> • Changes in the amount or colour of your urine • Swelling in your hands, ankles, or legs • Blood in urine • Painful urination 		<ul style="list-style-type: none"> • Severe nausea or vomiting • Feeling less hungry than usual • Pain on the right side of stomach • Yellowing of skin or whites of eye • Drowsiness • Dark urine (tea coloured) • Bleeding or bruising more easily than normal

INFLAMMATION OF HORMONE GLANDS (ESPECIALLY THE THYROID, ADRENALS, PITUITARY AND PANCREAS)



- Headaches that will not go away
- 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
- High blood sugar
- 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
- Fast heart rate or palpitations

INFLAMMATION OR PROBLEMS OF THE MUSCLES

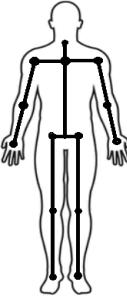




- Muscle weakness
- Tiredness and/or pain
- Rapid fatigue of the muscles, in one or more areas of your body
- Muscle stiffness

LOW NUMBER OF PLATELETS



- Unusual bleeding (e.g. nose or gum bleeding)
- Easy bruising

INFLAMMATION OF THE JOINTS		INFLAMMATION OF THE NERVES	
	<ul style="list-style-type: none"> • Joint pain • Swelling • Stiffness 		<ul style="list-style-type: none"> • Pain • Weakness • Paralysis in the hands, feet or arms • Numbness or tingling sensation • Problems with balance and coordination
INFUSION-RELATED REACTIONS			
	<ul style="list-style-type: none"> • Chills • Shaking • Itching • Rash • Flushing • Shortness of breath • Wheezing • Dizziness • Fever • Feeling like passing out • Back or neck pain • Facial swelling 		

Your doctor may give you other medicines to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of IMJUDO or stop your treatment with IMJUDO.

4. OTHER COMMON 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 3.**

If you get any side effects, talk to your doctor. (This includes any possible side effects not listed in this Patient Medication Guide.)

It is important to let your doctor know of any changes in your body. Talk to him/her about how you are currently feeling, new signs of side effects, or any other change. Remember, a small side effect can lead to something more serious if not treated.

Do not attempt to treat side effects yourself before talking to your doctor.

Most common side effects (may affect more than 1 in 10 people):

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

5. ADDITIONAL SAFETY INFORMATION

- If you get any side effects, talk to your doctor immediately. Getting medical treatment right away may help keep these problems from becoming more serious.
- Your doctor will assess you for these problems during your treatment with IMJUDO.
- If you visit the emergency room or doctor who is not your regular care team, it is important to tell them that you are getting an immunotherapy.