

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrJADENU®

deferasirox tablets

Read this carefully before you start taking **JADENU** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JADENU**.

Serious Warnings and Precautions

JADENU will be prescribed to you by a healthcare professional experienced in the treatment of chronic iron overload due to blood transfusions.

JADENU has not been studied in people with severe kidney and liver problems.

Serious side effects that can happen with the use of JADENU include:

- acute kidney failure
- liver failure
- ulcer or bleeding in the stomach or intestines

See the **Serious side effects and what to do about them** table, below for information on these and other serious side effects.

This medicine is also available as a tablet that is meant to be dissolved in liquid before drinking. The doses of these two formulations are not the same. Be sure you are taking the right type of deferasirox. Talk to your healthcare professional if you are not sure.

What is JADENU used for?

JADENU is used to treat chronic iron overload in:

- adult patients and children aged 6 years and older who receive blood transfusions for the treatment of anemias;
- children aged 2 to 5 years who receive blood transfusions for the treatment of anemias, and who cannot be adequately treated with deferoxamine;
- adult patients and children aged 10 years and older with thalassemia syndromes who do not require regular blood transfusions for the treatment of anemia.

How does JADENU work?

JADENU contains the medicinal ingredient deferasirox which is an iron chelating agent. It removes the excess iron from the body (also called iron overload). This reduces the risk of organ damage caused by iron overload.

What are the ingredients in JADENU?

Medicinal ingredient: deferasirox.

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, FD&C blue #2/Indigo carminine aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, poloxamer (188), polyethylene glycol (4000), povidone (K30), talc, titanium dioxide.

JADENU comes in the following dosage forms:

Film-coated tablets: 90 mg, 180 mg, 360 mg

Do not use JADENU if:

- you are allergic (hypersensitive) to deferasirox or any of the other ingredients of JADENU (see **What are the ingredients in JADENU?**)
- you have severe kidney disease.
- you have an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer.
- you have low levels of platelets in your blood.

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

- have severe heart problems (acute cardiac failure).
- have ulcers or bleeding in the stomach or intestines.
- are taking any medicines that can cause ulcers, such as:
 - non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids used to treat pain and inflammation
 - medicines used to treat osteoporosis
 - medicines used to prevent or treat blood clots
- have liver or kidney problems.
- have eye or vision problems.
- have hearing problems.
- have blood disorders (low level of platelets or white blood cells).
- have skin problems.
- are using any other iron chelation therapy to treat your iron overload.
- are 65 years of age or older. You may be more at risk of side effects.

Other warnings you should know about:

Serious Skin Reactions:

- JADENU can cause serious skin reactions, called severe cutaneous adverse reactions (SCARs), that can be fatal. These include:
 - Steven's Johnson syndrome (SJS)
 - toxic epidermal necrolysis (TEN)
 - hypersensitivity vasculitis
 - drug reaction with eosinophilia and systemic symptoms (DRESS)
 - erythema multiforme

- Symptoms can include rash, red skin, pain, swelling or blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and swollen lymph glands. If you notice any of these symptoms while you are taking JADENU, tell your healthcare professional immediately.

Children and Adolescents (age 2 years to 16 years):

- Your healthcare professional will monitor your child's growth and development during treatment with JADENU.
- Talk to your healthcare professional right away if your child becomes sick (vomiting, diarrhea or trouble drinking fluids) while taking JADENU. Your child may be dehydrated. If this happens, JADENU treatment may need to be interrupted. Your child will be treated for dehydration to prevent kidney problems.
- Treatment with JADENU can cause liver problems including liver failure that might lead to death in children. Liver failure has also happened with kidney problems in some children. Your healthcare professional will monitor how well your child's liver and kidneys are working.

Pregnancy and Breastfeeding:

- You should not take JADENU if you are pregnant unless clearly necessary.
- If you are pregnant, or think that you may be pregnant, talk to your healthcare professional.
- JADENU may make hormonal birth control less effective. This may put you at risk of getting pregnant. While you are taking JADENU you should use another form of birth control or use an additional barrier method, such as condoms. Talk to your healthcare professional about the birth control options that are right for you.
- You should not breastfeed during treatment with JADENU.

Driving and Using Machines:

- JADENU can cause dizziness. Give yourself time after taking JADENU to see how you feel before driving or operating any tools or machinery.

Blood Tests and Monitoring:

- You will have regular blood and urine tests before and during treatment with JADENU. You may also be assessed by Magnetic Resonance Imaging (MRI). These tests will monitor the amount of iron in your body (level of ferritin) to see how well JADENU is working. The tests will also monitor the health of your kidneys and liver.
- Your healthcare professional will decide when to perform these tests and will interpret the results. This will help to decide on the dose of JADENU that is right for you. They will also use these tests to decide when you should stop taking JADENU.
- Your eyesight and hearing will also be tested before you start taking JADENU and periodically during treatment.

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 JADENU:

- Antacids (medicines used to treat heartburn) containing aluminum should not be taken at the same time of day as JADENU.
- cyclosporine (used to help prevent organ rejection)
- simvastatin, cholestyramine (used to lower cholesterol)
- hormonal birth control
- medicines used to treat pain and inflammation (e.g. acetylsalicylic acid, ibuprofen, corticosteroids)
- oral bisphosphonates (used to treat osteoporosis)
- anticoagulant medicines (used to prevent or treat blood clots)
- repaglinide (used to treat diabetes)
- rifampicin (used to treat tuberculosis)
- paclitaxel (used in cancer treatment)
- phenytoin, phenobarbital (used to treat epilepsy)
- ritonavir (used in the treatment of HIV infection)
- theophylline (used to treat breathing problems such as asthma)
- busulfan (used as treatment prior to bone marrow transplant)

How to take JADENU:

- Always take JADENU exactly as your healthcare professional has told you. You should check with your healthcare professional if you are not sure.
- Take JADENU once a day, every day, at about the same time each day.
- JADENU should be taken on an empty stomach or with a light meal. Examples of light meals include: 1 whole wheat English muffin, 1 packet jelly (0.5 ounces), and skim milk (8 fluid ounces) or a turkey sandwich (2 oz. turkey on whole wheat bread with lettuce, tomato, and 1 packet mustard).
- Swallow the tablets whole with water or other liquids.
- If you have difficulty swallowing, JADENU tablets may be crushed and the full amount of medicine sprinkled in a soft food such as yogurt or applesauce. The food with the medicine should be immediately and completely consumed. Do not store it for future use.

Usual dose:

Your healthcare professional will decide on the dose that is right for you based on your body weight and the condition that is to be treated.

The daily dose of JADENU may be adjusted or interrupted. This will depend on how you respond to the treatment and if you experience certain side effects.

Overdose:

If you think you, or a person you are caring for, have taken too much JADENU, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

If you take too much JADENU you may have abdominal pain, diarrhea, nausea or vomiting. You may also have serious liver or kidney problems.

Missed Dose:

If you miss a dose, take it as soon as you remember on that day. Take your next dose as scheduled. Do not take a double dose on the next day to make up for the forgotten dose. Do not take more than one dose on the same day.

What are possible side effects from using JADENU?

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

Side effects may include:

- Gastrointestinal problems such as nausea, vomiting, diarrhea, pain in the abdomen, bloating, constipation, indigestion
- Skin rash
- Headache
- Dizziness
- Fever
- Sore throat
- Swelling of arms or legs
- Change in the colour of the skin
- Anxiety
- Sleep disorder
- Tiredness
- Hair loss

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Eye or vision problems: blurred or cloudy eyesight, partial loss of vision		✓	
Hearing problems: reduced hearing, hearing loss		✓	
Pancreatitis (inflammation of the pancreas): severe upper stomach		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
pain that lasts and gets worse when you lie down, nausea, vomiting			
Gastrointestinal bleeding: vomiting blood, black or tarry stools		✓	
Ulcer: frequent heartburn or abdominal pain particularly after eating or taking the drug		✓	
Blood problems (low white and/or red blood cells or platelets): feeling tired or weak, pale skin, bruising or bleeding for longer than usual after you cut yourself, fever, chills, mouth sores, frequent infections		✓	
RARE			
Acute renal failure (severe kidney problems): decreased urination, nausea, vomiting, swelling of extremities, fatigue		✓	
Allergic reactions: difficulty breathing or swallowing, dizziness, rash, hives, swelling of the face, lips, tongue or throat			✓
Serious skin reactions: severe rash, red or dry skin, pain, blisters and peeling skin that may start around the lips, nose, eyes, mouth and genitals and spread elsewhere, high fever, flu- like symptoms, swollen lymph glands, swelling of the face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine			✓
VERY RARE			
Liver problems: drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes, dark urine, pale stool, nausea, vomiting, loss of appetite		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Gastrointestinal perforation (a hole in the wall of your stomach or intestine): severe abdominal pain and tenderness, nausea, vomiting, chills, fever			✓

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

- Keep out of the reach and sight of children and of pets.
- Do not use JADENU after the expiry date which is stated on the package/carton after EXP. The expiry date refers to the last day of that month.
- Store at room temperature (15-30°C).
- Store in the original package in order to protect from moisture.

If you want more information about JADENU:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

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