

PART III: CONSUMER INFORMATION

PrJADENU®
(deferasirox tablets)

This leaflet is part III of a three-part "Product Monograph" published when JADENU® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JADENU. Contact your doctor or pharmacist if you have any questions about the drug.

Keep this leaflet. You may need to read it again. This medicine has been prescribed only for you or your child. Do not give it to anyone else or use it for any other illnesses.

ABOUT THIS MEDICATION**What the medication is 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.

What it does:

JADENU is an *iron chelating agent* which removes the excess iron from the body (also called iron overload), thereby reducing the risk of organ damage caused by iron overload.

When it should not be used:

- If you are allergic (hypersensitive) to deferasirox or any of the other ingredients of JADENU listed in the section *What the nonmedicinal ingredients are*.
- If you have severe kidney disease.
- If you have an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer.
- If you have low platelet count (<50 x 10⁹/L).

What the medicinal ingredient is:

The active substance is deferasirox.

What the nonmedicinal ingredients are:

core tablet: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, poloxamer (188), povidone (K30); film-coating material: FD&C blue #2/Indigo carminine aluminum lake, hypromellose, polyethylene glycol (4000), talc, titanium dioxide.

What dosage forms it comes in:

JADENU is supplied as film-coated tablets. Each tablet contains 90 mg, 180 mg or 360 mg deferasirox.

JADENU (deferasirox) is supplied in blisters of 30 film-coated tablets (3 blisters of 10 tablets per box).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

JADENU should be prescribed by doctors experienced in the treatment of chronic iron overload due to blood transfusions.

JADENU has not been studied in patients with severe kidney and liver problems (impairment).

Serious adverse events with the use of JADENU include:

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

JADENU is a new formulation of deferasirox. The dose and how this medication is taken are different compared to EXJADE® dispersible tablets.

BEFORE you use JADENU talk to your doctor or pharmacist if you have:

- severe heart problems (acute cardiac failure)
- ulcer or bleeding in the stomach or intestines
- liver or kidney problems
- visual (eye) problems
- hearing problems
- blood disorders (a low level of platelets or white blood cell count)
- skin problem

During treatment with JADENU, talk to your doctor or pharmacist immediately if you have:

- Rash, red skin, pain, swelling or blistering of the lips, eyes or mouth, skin peeling, high fever and flu-like symptoms and swollen lymph glands. If you get these symptoms, your doctor may stop your treatment.

Older people (age 65 years and over):

Elderly patients may experience more side effects than younger patients. They should be monitored closely by their doctor for side effects that may require a dose adjustment.

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

Their growth and development need to be monitored during treatment with JADENU.

Pregnancy and breast-feeding:

JADENU is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor. JADENU may decrease the effect of hormonal contraceptives, and you may be at risk of getting pregnant if you are taking a hormonal contraceptive.

Breast-feeding is not recommended during treatment with JADENU.

Driving and using machines:

If you feel dizzy after taking JADENU, do not drive or operate any tools or machines until you are feeling normal again.

You should receive regular blood and urine tests before and during treatment with JADENU. You may also be assessed by Magnetic Resonance Imaging (MRI). These will monitor the amount of iron in your body (level of ferritin) to see how well JADENU is working. The tests will also monitor your kidney function (blood level of creatinine, presence of protein in the urine) and liver function (blood level of transaminases, bilirubin and alkaline phosphatase). Your doctor will take these tests into consideration when deciding on the dose of JADENU most suitable for you and will also use these tests to decide when you should stop taking JADENU.

Your eyesight and hearing will also be tested before and periodically during treatment as a precautionary measure.

The safety of JADENU when administered with other iron chelation therapy has not been established.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs (obtained without a prescription), vitamins and natural products. Some medicines may interact with JADENU:

- Antacids (medicines used to treat heartburn) containing aluminum should not be taken at the same time of day as JADENU.

In particular tell your doctor if you are taking any of the following:

- cyclosporine (used in transplantation to prevent graft rejection or for any other condition)
- simvastatin (used to lower cholesterol)
- hormonal contraceptive agents (birth control medicines)
- certain painkillers or anti-inflammatory medicines (e.g. acetylsalicylic acid, ibuprofen, corticosteroids)
- oral bisphosphonates (used to treat osteoporosis)
- anticoagulant medicines (used to prevent or treat blood clotting)
- 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)
- cholestyramine (used mainly to lower cholesterol)

- theophylline (used to treat respiratory diseases such as asthma)
- busulfan (used as treatment prior to bone marrow transplant)

PROPER USE OF THIS MEDICATION

Always take JADENU exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual dose:

For patients receiving regular blood transfusion:

- Initial dose: 7 mg, or 14 mg, or 21 mg per kg body weight daily.
- Maximum dose: 21 mg per kg body weight daily.

For patients with thalassemia syndromes who do not require regular blood transfusions:

- Initial dose: 7 mg per kg body weight daily.
- Maximum dose: 14 mg per kg body weight daily.

The daily dose will be adjusted depending on how you respond to the treatment.

When to take JADENU

- Take JADENU once a day, every day, at about the same time each day.

How to take JADENU:

JADENU should be taken on an empty stomach or with a light meal, preferably at the same time each day. 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.

Overdose:

If you have taken too much JADENU, or if someone else accidentally takes your tablets, contact your doctor or go to the hospital or contact your local poison control centre. Show them the blister package of tablets. Medical treatment may be necessary.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, JADENU can cause side effects.

Some side effects are common.

These side effects may affect between 1 and 10 in every 100 patients.

- Gastrointestinal disorders, such as nausea, vomiting, diarrhea, pain in the abdomen, bloating, constipation, indigestion
- Skin rash
- Headache

Other side effects are uncommon.

These side effects may affect less than 1 in every 100 patients.

- Dizziness
- Fever
- Sore throat
- Swelling of arms or legs
- Change in the colour of the skin
- Anxiety
- Sleep disorder
- Tiredness
- Hearing loss
- Vision change (early cataracts)
- Ulcer and/or bleeding in the stomach or intestine
- Liver disorders
- Traces of blood and/or protein in the urine
- Hair loss

You will have some blood tests while taking JADENU. Your doctor will look for any changes in kidney function, liver function, or in blood cell counts.

Your doctor may also want to test your eyesight and hearing while you are taking JADENU.

You may notice other side effects not listed in this leaflet. If you are concerned with any side effect, or if any side effect makes you feel unwell, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Uncommon			
Blurred or cloudy eyesight		√	
Reduced hearing		√	
Severe upper stomach pain (sign of pancreatitis)		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Vomiting blood and/or have black stools		√	
Frequent heartburn or abdominal pain (signs of ulcers) particularly after eating or taking the drug		√	
Rare			
Acute renal failure (severe kidney problems), decreased urine output (sign of kidney problem)		√	
Difficulty breathing, dizziness, rash or swelling of the face and throat (signs of allergic reaction)			√
Frequent heartburn		√	
Partial loss of vision		√	
Rash, red skin, pain, blistering of the lips, eyes or mouth, skin peeling, high fever flu- like symptoms and swollen lymph glands (signs of serious skin reaction)			√
Very rare			
Drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems)		√	
Unknown frequency			
Tear in stomach or intestine wall that can be painful and cause nausea			√

This is not a complete list of side effects. For any unexpected effects while taking JADENU contact your doctor or pharmacist.

HOW TO STORE IT

- 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.novartis.ca>
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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November 26, 2018