

PART III: CONSUMER INFORMATION**PrEXJADE®**

(deferasirox dispersible tablets)

This leaflet is part III of a three-part "Product Monograph" published when **EXJADE®** was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EXJADE. 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:**

EXJADE 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:

EXJADE 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 (in particular, lactose) of EXJADE 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 ($<50 \times 10^9/L$).

What the medicinal ingredient is:

The active substance is deferasirox.

What the nonmedicinal ingredients are:

Lactose monohydrate, crospovidone, povidone, sodium lauryl sulphate, microcrystalline cellulose, silicon dioxide and magnesium stearate.

What dosage forms it comes in:

EXJADE is supplied as tablets for oral suspension. Each tablet contains 125 mg, 250 mg or 500 mg deferasirox.

Each blister package contains 28 dispersible tablets.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

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

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

Serious adverse events with the use of EXJADE include:

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

BEFORE you use EXJADE 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.
- severe intolerance to lactose (milk sugars). EXJADE tablets contain lactose.
- visual (eye) problems.
- hearing problems.
- blood disorders (a low level of platelets or white blood cell count).
- skin problem.

During treatment with EXJADE, 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.
- Vision and hearing problems.

Older people (65 years of age and above):

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 EXJADE.

Pregnancy and breast-feeding:

EXJADE is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor. EXJADE may decrease the effect of hormonal contraceptives, and you may be at risk of getting pregnant if you are taking a hormonal contraceptive. You should use an additional or different type of contraception.

Breast-feeding is not recommended during treatment with EXJADE.

Driving and using machines:

If you feel dizzy after taking EXJADE, 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 EXJADE. 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 EXJADE 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 EXJADE most suitable for you and will also use these tests to decide when you should stop taking EXJADE.

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

The safety of EXJADE 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 EXJADE:

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

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 EXJADE 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: 10 mg, or 20 mg, or 30 mg per kg body weight daily.
- Maximum dose: 30 mg per kg body weight daily.

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

- Initial dose: 10 mg per kg body weight daily.
- Maximum dose: 20 mg per kg body weight daily.

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

When to take EXJADE

- Take EXJADE once a day, every day, at about the same time each day;
- Must be taken on an empty stomach;
- Then wait at least 30 minutes before eating the first meal of the day.

How to take EXJADE:

- **Drop** the tablet(s) into a glass of water, orange or apple juice (100 mL for doses of less than 1 g, and 200 mL for doses of 1 g or more).
- **Stir** until the tablet(s) dissolve completely. The liquid in the glass will look cloudy.
- **Drink** everything in the glass. Then add a little water or juice to what is left in the glass and drink that too.



Do not dissolve the tablets in fizzy drinks or milk.

Do not chew, break or crush the tablets. Do not swallow the tablets whole.

Overdose:

If you have taken too much EXJADE, or if someone else accidentally takes your tablets, contact your doctor or go to the hospital or contact your local poison control centre. Show the doctor the blister package of tablets. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhea,

nausea and vomiting, and kidney or liver problems that can be serious.

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, EXJADE can cause side effects.

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

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
- A decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anaemia aggravated), and in the number of white blood cells (neutropenia)

You will have some blood tests while taking EXJADE. 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 EXJADE.

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)		√	
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 EXJADE contact your doctor or pharmacist.

HOW TO STORE IT

- Keep out of the reach and sight of children and of

pets.

- Do not use EXJADE 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 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.

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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