CONSUMER INFORMATION

EXJADE®, for use in:

- the management of chronic iron overload in patients with transfusion-dependent anemias aged six years or older;
- the management of chronic iron overload in patients with transfusion-dependent anemias aged two to five who cannot be adequately treated with deferoxamine,

has been approved with conditions, pending the results of studies to verify its clinical benefit.

EXJADE® has received non-conditional marketing authorization for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and older.

For more information, patients are advised to contact their health care provider.

What is a Notice of Compliance with Conditions (NOC/c)?
An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

Pr EXJADE®

(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 contains 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, skin reddening, pain, swelling or blistering of lips, eyes or mouth, skin peeling and flu-like symptoms. 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 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.

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.

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®.
- Other iron chelating agents should not be taken while on treatment with EXJADE®, as the safety and efficacy of a combination with EXJADE® has not been established.

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)

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 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 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, EXJADE® 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
- Severe rash/skin disorders
- 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 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®.

If any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet, 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	
Common			

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**	
Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling, sore throat (signs of severe skin reaction).		√	
Uncommon			
Blurred or cloudy eyesight		√	
Reduced hearing		√	
Vomiting blood and/or have black stools.		√	
Frequent heartburn or abdominal pain (ulcers) particularly after eating or taking the drug		√	
Rare			
Acute renal failure (severe kidney problems), decreased urine output (sign of kidney problem)		√	
Rash, difficulty breathing, dizziness or swelling of the face and throat (signs of allergic reaction)	√		
Frequent heartburn		√	
Partial loss of vision		√	
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			
Formation of a hole in the stomach or intestine wall			√

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 (15-30ºC).
- 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

PrEXJADE® is a registered trademark

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February 11, 2015