PART III: CONSUMER INFORMATION

PrDESFERAL®

(deferoxamine mesylate for injection, Novartis Std.)

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

ABOUT THIS MEDICATION

What the medication is used for:

DESFERAL is used in the treatment of following conditions:

- acute iron poisoning as an adjunct to the standard treatments,
- chronic iron overload due to frequent blood transfusion,
- chronic aluminum overload in patients with end-stage kidney failure required dialysis.

DESFERAL is also used to test for aluminum overload.

What it does:

DESFERAL contains the active substance deferoxamine, which is a so-called "chelator". It works by biding to excess iron or aluminum in the blood and removing them from the body (through the urine and feces).

When it should not be used:

- If you are allergic (hypersensitive) to deferoxamine.

What the medicinal ingredient is:

Deferoxamine mesylate.

What the nonmedicinal ingredients are:

Not applicable. The DESFERAL vials contain the medicinal ingredient deferoxamine mesylate without non-medicinal ingredients.

What dosage forms it comes in:

DESFERAL is available as 500 mg lyophilized powder for injection in vials.

WARNINGS AND PRECAUTIONS

The treatment with DESFERAL should be started and followed up by a doctor experienced in the treatment of chronic iron or aluminum overload.

BEFORE you use DESFERAL talk to your doctor or pharmacist if you:

- have any hearing or eye sight problems. DESFERAL may cause hearing problems and eye sight problems;
- have high blood sugar (diabetes);
- have blood clotting problems;
- have any neurological problems (convulsion, dementia);
- severe kidney problem that does not required dialysis;
- lung disease or problem breathing;
- are pregnant or planning to become pregnant. DESFERAL can harm the unborn child, especially if it is used during the first 3 months of pregnancy. If the treatment with DESFERAL is needed, female patients who can get pregnant should use an effective birth control method before starting, while taking, and for at least one month after the last treatment with DESFERAL;
- are breastfeeding.

DESFERAL may reduce growth rate. Patients under 16 years of age should be monitored for body weight and height every three months.

Increased risk of eye disorders have been reported in patients older than 65 years of age.

Effects on ability to drive or use machines:

DESFERAL may affect your sight or hearing, make you feel dizzy, or cause other disturbances of nervous function. If you experience such effects, you should not drive or use machines.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines in addition to DESFERAL, including medicines obtained without a prescription. You may need to change the dosage or stop taking one of the medicines.

Drugs that may interact with DESFERAL include:

- medicines containing prochlorperazine, a neuroleptic drug used to treat neurological disorders
- vitamin C
- erythropoietin
- gallium-67, a medicine given before imaging (scanning, which is used in diagnosis of certain diseases)

In patients without heart failure, their doctor may tell them to take vitamin C one month before and during regular treatment with DESFERAL. The maximum daily dose of vitamin C should not exceed 200 mg for adult patients, 100 mg in older children and 50 mg for children under 10 years of age. However, their doctor also needs to monitor their heart function.

PROPER USE OF THIS MEDICATION

Your doctor has chosen the right dose and method of administration for your particular condition. Follow your doctor's instructions carefully. Make sure you use the medication exactly as your doctor tells you.

Usual dose:

Acute iron poisoning

DESFERAL can be used in cases of poisoning with iron preparations. This treatment is carried out in hospital.

Chronic iron overload
Daily doses of 20 to 60 mg per kilogram bodyweight. DESFERAL can be given by slow infusion under the skin (subcutaneously), by infusion into a vein (intravenously), or by injection into a muscle (intramuscularly).

Chronic aluminum overload in patients with severe kidney disease
DESFERAL is usually given once a week by slow infusion into a vein during the last 60 minutes of a dialysis session, or 5 hours before a dialysis session, depending on the aluminum concentration in your blood.
The dose of DESFERAL is 5 mg per kilogram of bodyweight.

The duration of treatment and any change in your individual dose of DESFERAL will depend on the results of the tests carried out by your doctor.

Diagnosis of aluminum overload
If you are receiving dialysis, your doctor will want to test whether you have aluminium overload. You will be given 5 mg of DESFERAL per kilogram of bodyweight by slow infusion into a vein during the last 60 minutes of a dialysis session. The aluminium content of blood samples taken just before this dialysis session and the next one will be determined.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed a dose of DESFERAL, tell your doctor at once.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, DESFERAL can cause side effects. The following are the possible side effects of DESFERAL:

Very common side effects: (affecting more than 10 in 100 patients)
- injection site reaction such as pain, swelling, reddening, itching of the skin, eschar (dead tissue that sheds from healthy skin), crust formation, small blisters, burning
- joint or muscle pain

Common side effects: (affecting more than 1 and less than 10 in 100 patients)
- nausea
- headache
- itchy rash
- fever
- reduced growth rate, bone disorders

Uncommon side effects: (affecting between 1 and 10 in 1000 patients)
- vomiting
- abdominal pain

Very rare side effects: (affecting less than 1 in 10,0000 patients)
- diarrhea
- skin rash
- sensation of numbness or tingling in fingers and toes

Unknown frequency:
- muscle spasms
- abnormal liver or kidney function test results
- a low blood level of calcium, and worsening hyperparathyroidism in patients treated for aluminum overload
- reddish-brown urine
- low blood pressure, increased heart rate and shock

If any of the side effects gets serious or you experience 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	
Uncommon			
Disturbances of hearing such as ringing or noise in the ears, hearing loss		√	
Rare			
Disturbances of vision such as blurred eyesight, abnormal colour vision, night blindness, black spots in the vision, loss of vision, clouding of the lens of the eye, visual field defects or decreased sharpness of vision		√	
Fungal or bacterial infections leading to high fever, shortness of breath, acute diarrhea, abdominal pain, general discomfort or sore throat		√	
Dizziness, light-headedness (signs of low blood pressure that can occur when the drug is given too rapidly)		√	
Very rare			

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**
Breathlessness due to lung disorders		√	
Unusual bleeding/bruising (a sign that levels of blood platelets are low)	√		
Fever, sore throat or mouth ulcers due to infections (a sign that levels of white blood cells are low)	√		
Rash, itching, hives, difficulty breathing or swallowing, feeling of tightness in the chest with wheezing or coughing, dizziness, swelling mainly of the face and throat (signs of a severe allergic reaction or asthma)		√	
Disturbances of the nervous system		√	
Unknown			
Severely decreased output of urine (sign of a kidney problem)		√	
Convulsions (mainly in patients on dialysis)		√	

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

HOW TO STORE IT

- Keep out of reach and sight of children and pets.
- Do not use DESFERAL after the expiry date shown on the pack.
- Store the DESFERAL vials containing the dry active substance between 15-25 °C. Do not store above 25°C.
- One vial is for single use only. The product should be used immediately after the solution has been made up (reconstituted), i.e. treatment should start within 3 hours. When the solution has been prepared under recognized sterile conditions, it may be stored for a maximum period of 24 hours at room temperature before the start of treatment. Opaque or cloudy solutions should be discarded.
- Remember to return any unused vials to your pharmacist.

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/adverse-reaction-reporting.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.

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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