

**DESFERAL<sup>®</sup> 500 VIALS**

**(desferrioxamine mesylate)**

Powder for solution for injection

Patient Information Leaflet

Document status: Final

Approval date: 10 August 2022

**SCHEDULING STATUS: S4**

**DESFERAL 500 mg (Dry powder vials)**

Desferrioxamine mesylate

**Read all of this leaflet carefully before you start using DESFERAL**

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.**
- **DESFERAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

**What is in this leaflet**

1. What DESFERAL is and what it is used for
2. What you need to know before you use DESFERAL
3. How to use DESFERAL
4. Possible side effects
5. How to store DESFERAL
6. Contents of the pack and other information

## **1. What DESFERAL is and what it is used for**

Desferal contains the active substance desferrioxamine which is a so-called “chelator”. It is used to remove excess iron or aluminum from the body.

Repeated blood transfusions may be necessary in patients suffering from a blood disorder called thalassaemia. However, repeated blood transfusions can cause a build-up of excess iron. This is because blood contains iron and the body does not have a natural way to remove the excess iron that comes with blood transfusions. Over time, the excess iron can damage important organs such as the liver and heart. DESFERAL removes this excess iron and can therefore be used to treat iron overload. DESFERAL can be used to treat adults and children.

It can also be used to:

- treat acute iron poisoning,
- treat chronic aluminum overload in patients with severe kidney disease who require regular dialysis. Under certain circumstances, dialysis can lead to an excess build-up of aluminum.
- Test for iron storage disease or aluminum overload.

## **2. What you need to know before you take DESFERAL**

### **Do not use DESFERAL:**

- If you are allergic (hypersensitive) to desferrioxamine (except where successful desensitization makes Desferal treatment possible).
- If you are pregnant
- If you are breastfeeding

## Warnings and precautions

Tell your doctor or health care provider before using DESFERAL:

- If you have any kidney disorders.

Tell your doctor immediately if you get any of the following symptoms during treatment with DESFERAL:

- If you experience dizziness, light-headedness (signs of low blood pressure), breathlessness that can occur if the drug is given too rapidly when DESFERAL is administered by infusion into a vein.
- If you experience visual and hearing disorders.
- If you experience severely decreased urine output (sign of kidney disorders).
- If you experience high fever, sore throat, shortness of breath, abdominal pain, acute diarrhoea or general discomfort (signs of fungal or bacterial infections).
- If you experience fatigue, palpitation, shortness of breath, or swelling (edema) in your legs, ankles and feet (symptoms of heart disorders), which may occur in patients who use DESFERAL and also take high doses of Vitamin C. If your doctor prescribes vitamin C supplements, make sure you have been using DESFERAL regularly for at least 1 month before you start taking vitamin C. Also, take vitamin C only in the doses recommended by your doctor.
- Do not exceed the daily dose of 200 mg of vitamin C.

Please note that your urine may turn reddish-brown during treatment with DESFERAL. This is because there is more iron in your urine. This is usually nothing to worry about, but if you are worried, talk to your doctor or nurse.

### **Children**

Tell your doctor if you notice that:

- Your child treated with DESFERAL has slower than normal growth.

### **Other medicines and DESFERAL**

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

This includes in particular:

- medicines containing prochlorperazine, a neuroleptic drug used to treat neurological disorders,
- vitamin C (doses above 200 mg daily during treatment with DESFERAL). Do not take more than 200 mg of vitamin C per day (see above section 2),
- gallium-67, a medicine given before imaging (scanning), which is used in diagnosis of certain diseases.
- You may need to change the dosage of the other medicine, or stop taking it altogether.

### **Pregnancy and breastfeeding**

You should not be treated with DESFERAL if you are pregnant or if you are planning to become pregnant.

You should not breastfeed your baby while using DESFERAL.

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

### **Driving and using machines**

DESFERAL may affect your sight or hearing, make you feel dizzy, or cause other disturbances of nervous function. If you experience such effects, do not drive or operate any tools or machines until you feel well again.

### **3. How to use DESFERAL**

Do not share medicines prescribed for you with any other person.

Always use DESFERAL exactly as your doctor has told you. Check with your doctor if you are not sure.

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

Your doctor will calculate the dose you need and tell you how much DESFERAL to use.

Depending on how you respond to treatment, your doctor may suggest a higher or lower dose.

DESFERAL is intended for use as a solution in water for injection(s). Dissolve DESFERAL powder in the "water for injection" that your pharmacist has given you. At the recommended

concentration of 95 mg/mL (for subcutaneous injection), the solution appears colorless to slightly yellowish. The solution should be clear. Do not use opaque or cloudy solutions.

### **Treatment for iron overload**

Your doctor will adjust the dose to your particular condition. In most patients, the daily dose is 20 to 60 mg per kilogram body weight.

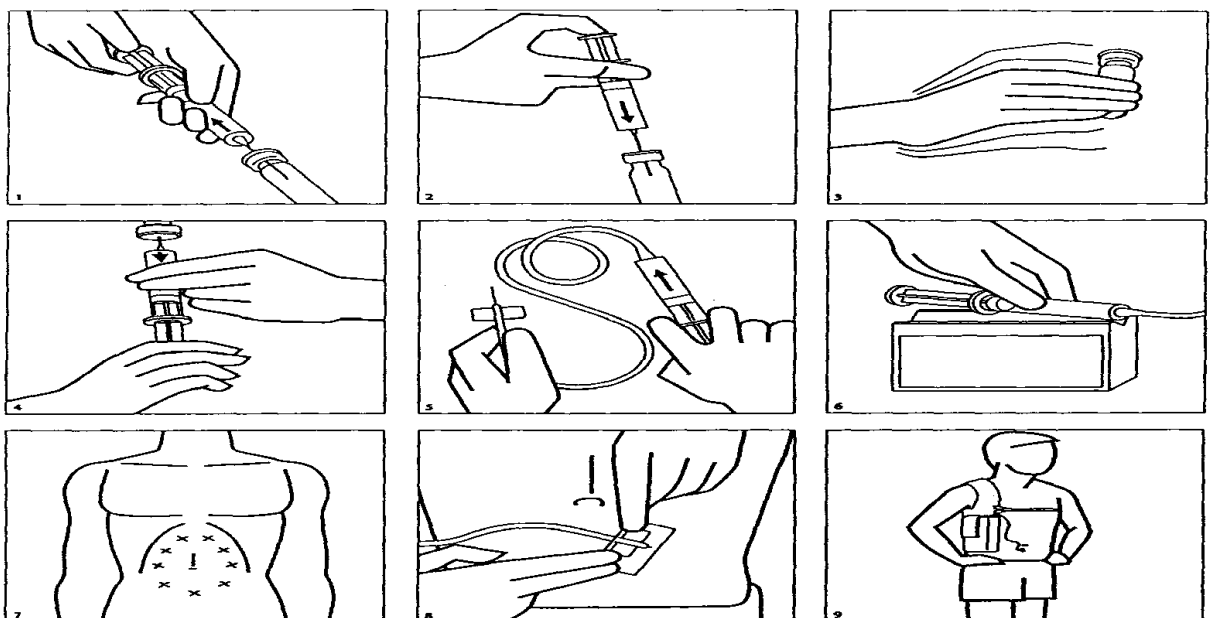
Desferal can be given by slow infusion, under the skin (subcutaneous injection using an infusion pump), by infusion into a vein, or by injection into a muscle.

Your doctor or nurse may prepare your injection for you, or you may be taught how to do so yourself. For long-term treatment of iron overload, it is particularly convenient to give DESFERAL slowly under the skin for 8 to 12 hours (e.g. overnight), using a portable light-weight infusion pump. DESFERAL is usually used with a pump 5 to 7 times a week. The pump should be set up carefully under very clean conditions.

Follow the instructions below for preparing the solution and infusing it under the skin:

1. Draw the water for injection into a syringe.
2. After cleaning the rubber stopper of the DESFERAL vial with alcohol, inject the content of the syringe into the vial.
3. Shake the vial thoroughly to dissolve the powder.
4. Draw the solution so obtained into the syringe.

5. Attach the extension tube to the syringe, connect the extension tube to the butterfly-type needle, and then fill the empty space in the tube with the solution in the syringe.
6. Place the syringe in the infusion pump.
7. For infusion you may insert the butterfly-type needle under the skin of the abdomen, arm, upper leg or thigh. It is important to first clean the skin very thoroughly with alcohol. Then insert the needle firmly, up to the wings, into a fold of the skin formed by your free hand. The tip of the needle should move freely when the needle is waggled. If it doesn't move freely, the tip of the needle may be too close to the skin. Try again at a new site after cleaning it with alcohol.
8. Then fix the needle and tape it down.
9. Patients usually wear the pump on the body using a belt or shoulder holster. Many patients consider overnight use to be most convenient.



### **Concomitant use of vitamin C**

After you have had at least one month of regular treatment with DESFERAL, your doctor may decide that you should take vitamin C also. The maximum daily dose of vitamin C for adults is 200 mg, which is broken up into smaller doses that are taken over the course of the day.

50 mg vitamin C daily is usually sufficient for children under 10 years of age, while 100 mg will generally be sufficient for older children.

### **Treatment for acute iron poisoning**

To treat iron poisoning DESFERAL is usually given intravenously (injected into the vein).

The recommended dose is 15 mg/kg body weight every hour. This may be reduced after 4 to 6 hours. The maximum recommended dose is 80 mg/kg body weight (for both children and adults) every 24 hours.

### **Treatment for chronic aluminum overload**

- DESFERAL is usually given once a week, by slow infusion into a vein, either during the last 60 minutes of a dialysis session, or 5 hours before a dialysis session, depending on the level of aluminium in your blood.
- If you are receiving continuous ambulatory peritoneal dialysis (CAPD) or continuous cyclic peritoneal dialysis (CCPD), you will need to take your dose of DESFERAL prior to the final exchange of the day.
- The dose of DESFERAL is 5 mg per kilogram of body weight.

Your doctor will arrange for you to be tested in order to determine how long you should be treated, and whether the dose of DESFERAL needs to be changed.

### **Testing of iron storage disease or aluminum overload**

- If you have to undergo testing for iron overload, you will be given an intramuscular injection of DESFERAL and will be asked to collect your urine for 6 hours. The urine will then be checked for iron.
- If you have to undergo testing for aluminum overload, you will be given a slow intravenous infusion of DESFERAL during the dialysis session. The aluminum content of blood samples taken just before this dialysis session and the next one will be determined.

Your doctor will tell you how long your treatment with DESFERAL will last. Do not stop treatment early because this may affect your condition. If you have the impression that the effect of DESFERAL is too strong or too weak, tell your doctor or pharmacist.

### **If you use more DESFERAL than you should**

Do not use a higher dose or concentration than the one recommended by your doctor, as you may experience local side effects at the injection site, as well as some other side effects such as dizziness, light-headedness (signs of low blood pressure), fast or slow heartbeat, gastrointestinal disorders (nausea), severely decreased urine output (sign of kidney disorder),

nervous system disorders (e.g. agitation, inability to speak, headache), breathlessness (sign of lung disorders), visual and hearing disorders.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to use DESFERAL**

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

### **4. Possible side effects**

DESFERAL can have side effects.

**Some side effects could be serious. Tell your doctor straight away**, if you experience any of the side effects listed below:

#### **Less frequent:**

- disturbances of hearing, such as ringing or noise in the ears, hearing loss
- sudden difficulty breathing and feeling of tightness in chest with wheezing or coughing (asthma)
- 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 infection leading to high fever, shortness of breath, cough with blood, diarrhoea, abdominal pain, vomiting, nausea or sore throat
- dizziness, light-headedness (signs of low blood pressure that can occur when the drug is given too rapidly)
- 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)
- disturbances of speech, cognition, movement, affect, or behavior (signs of a brain disorder)
- bacterial infection leading to fever, abdominal pain, and diarrhoea which may have blood in the stool
- severely decreased output of urine (sign of a kidney problem)
- seizures or fits (convulsions) which may occur mainly in patients on dialysis

**Other possible side effects are listed in the table below**

**Tell your doctor**, if any of the side effects listed below affects you severely:

Frequent	Injection site reactions such as pain, swelling, reddening, itching of the skin, scab, small blisters. Joint or muscle pain, nausea, headache, itchy rash, fever, reduced growth rate, bone disorders.
Less frequent	Vomiting, abdominal pain, diarrhoea, skin rash, sensation of numbness or tingling in fingers and toes, muscle spasms, abnormal liver or kidney function test results, hypocalcaemia and aggravation of hyperparathyroidism in patients treated for aluminum overload. Your urine may turn reddish-brown because there is more iron in your urine. This is usually nothing to worry about, but if you are worried, you should talk to your doctor or nurse.

Not all side effects reported for DESFERAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DESFERAL, please consult your health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.SAHPRA.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DESFERAL.

## **5. How to store DESFERAL**

Store at or below 25 °C.

Once prepared, solutions of DESFERAL should be stored at room temperature (23 °C or below) for not longer than 24 hours.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What DESFERAL contains**

The active substance is desferrioxamine mesylate.

### **What DESFERAL looks like and contents of the pack**

Each vial contains a white to practically white powder supplied in a clear glass vial. Packs

Contain ten 500 mg vials.

**Holder of Certificate of Registration:**

NOVARTIS SOUTH AFRICA (PTY) LTD

Magwa Crescent West Waterfall City,

Jukskei View Johannesburg

2090

**This leaflet was last revised in**

10 August 2022

**Reference number**

H2791 (Act 101/1965)