Package leaflet: Information for the patient

Desferal® 500mg Vials Powder for Solution for Injection or Powder for Concentrate for Solution for Infusion.
Desferoxamine mesilate

Read all of this leaflet carefully before you are given this medicine - because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Desferal is and what it is used for

The full name of your medicine is desferoxamine mesilate. In this leaflet the shorter name Desferal will be used.

Desferal is an injection used when you have too much iron or aluminium in your blood (iron or aluminium overload). It is a "chelating" agent. This means that it sticks to the unwanted iron or aluminium in the blood to form a compound which the body can get rid of safely.

You may have too much iron or aluminium in your blood after iron poisoning or as a side effect of blood transfusions or kidney dialysis. Certain illnesses can also have the same effect. The aim here is to balance out your levels and avoid an overload occurring. In older people, iron may be removed from the blood in order to encourage a slow release of iron from body stores that have already reached a toxic level.

Desferal can also be used to test whether you have too much or too little iron or aluminium in your body.

2. What you need to know before you are given Desferal

Do not have Desferal if:
- You are allergic to desferoxamine mesilate or any of the other ingredients of this medicine (listed in section 6).

Do not have Desferal if the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before having Desferal.

Warnings and precautions
Talk to your doctor, nurse or pharmacist before having Desferal if:
- you have kidney problems or are on dialysis, especially if you are elderly
- you have been told by your doctor that aluminium has affected your nerves. If so you may be

given a dose of clonazepam before you are given Desferal
- you have been told by your doctor that you have “hyperparathyroidism”
- you have heart problems.

If any of the above apply to you (or you are not sure), talk to your doctor, nurse or pharmacist before having Desferal.

Other medicines and Desferal
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following medicines:
- prochlorperazine used for dizziness, sickness or mood problems
- erythropoietin used for anaemia, especially in people who are on dialysis
- vitamin C.

If any of the above apply to you (or you are not sure), talk to your doctor, nurse or pharmacist before having Desferal.

Medical check-ups during treatment with Desferal
- Your doctor will be checking your progress carefully during treatment with Desferal and may want to do certain tests of your blood and urine from time to time.
- If you have Desferal for a long time or you have kidney problems and are on dialysis, your doctor may want to give you regular eye tests and hearing tests. This is because Desferal can affect your vision and your hearing. These tests are usually done every 3 months. If you notice any problems with your sight or hearing at any time you should stop taking Desferal and tell your doctor straight away.
- In children under the age of 3 years high doses of Desferal may affect growth. Regular checks on body weight and height are, therefore, recommended in children using Desferal. These checks are usually done every 3 months.

Pregnancy and breast-feeding
Talk to your doctor before having this medicine if you are pregnant, might become pregnant or are breast-feeding. If you become pregnant while you are being treated with Desferal you must tell your doctor straight away.

Driving and using machines
Desferal can make you feel dizzy or drowsy. It can also affect your vision or hearing. You must not drive, cycle, operate machinery or do anything else which requires concentration until you know how your medicine affects you.

3. How you are given Desferal

Your doctor will decide what dose of Desferal you need and when you should have it. The dose will be on the pharmacist’s label. Check the label carefully. If you are not sure ask your doctor, nurse or pharmacist.

Treatment with Desferal
A doctor or nurse may prepare your injection for you, or you may be taught how to do this yourself. The Desferal powder in the vial should be dissolved in the “water for injection” that your pharmacist has given you. This will make a clear, colourless to slightly yellow solution.

Treatment with the solution should start within 3 hours of it being made. If the solution has been made under sterile conditions (for instance in a hospital), it may be stored in the fridge for up to 24 hours before being used.

Any unused Desferal should be thrown away.

Ways in which you may be given Desferal
You may have Desferal in different ways, for example:

- by injection into a muscle. This is called being given "intramuscularly"
- by injection into a vein. This is called being given "intravenously". It should be given slowly over a period of time rather than all in one go. This is called a "slow infusion"
- by injection under your skin. This is called being given "subcutaneously". It may be given over a period of time using a special pump. This is called an "infusion"
- by injection into the peritoneum (the membrane that lines the abdominal cavity and forms the outer coating of the abdominal organs). This is called "intraperitoneal administration". This way is recommended for patients who need treatment and are also on dialysis (but the other routes can also be used when necessary). You will be monitored closely by your doctor or nurse.

How much you will be given
The dose that you need will depend on why you are having Desferal and how well your body is currently getting rid of the iron or aluminium. Your doctor will work out exactly how much Desferal you need.

The usual doses of Desferal are as follows:

- **Iron Poisoning**
  To treat iron poisoning Desferal is usually given "intravenously" (injected into a vein). The recommended dose is 15 mg for each kg of body weight every hour. This may be reduced after 4 to 6 hours. The maximum recommended dose is 80 mg for each kg of body weight every 24 hours.

- **Iron Overload**
  Your doctor will work out exactly how much Desferal you will need. This will depend on how much extra iron you have in your body. Desferal is usually given "subcutaneously" (a slow injection under the skin). It can sometimes be given "intramuscularly" (injected into the muscle) though. The dose is usually between 20 and 60 mg for each kg of body weight. It is usually given between 5 and 7 times a week, depending on how much extra iron you have in your body.

  In children under 3 years of age the average daily dose is not usually more than 40 mg for each kg of body weight.

- **Aluminium Overload**

  The exact dose of Desferal that you need will depend on how much extra aluminium you have in your body. Your doctor or nurse will do tests to work this out. Desferal is usually given by slow "intravenous" injection.

  If you are on dialysis the usual dose of Desferal is 5 mg for each kg of body weight. This is normally given once a week. When you are given Desferal will depend on how much extra aluminium you have in your body. It will either be given during the last hour of your dialysis or 5 hours before your dialysis starts.

- **Testing to see if you have got too much iron in your body**

  Desferal is usually given "intramuscularly" (injected into a muscle). The usual dose is 500 mg. After you have had your Desferal, your doctor or nurse will probably want you to collect urine samples for about 6 hours. They will then do tests on your urine to see how much iron is in it.

- **Testing to see if you have got too much aluminium in your body if you are on dialysis**

Your doctor or nurse will probably take a blood sample from you before you are given Desferal. This will be taken just before your dialysis. Tests will be done on the blood to see how much aluminium is in it.

The usual dose of Desferal is 5 mg for each kg of body weight. It is usually given during the last hour of your dialysis.

Another blood test will probably be taken before your next session of dialysis to check how much aluminium is in your blood.

If you are given more Desferal than you should
If you think you have been given more Desferal than you should, tell your doctor, nurse or pharmacist straight away. You might:

- get a headache, fast or slow heart beat, temporary loss of sight, speech, stomach or kidney problems
- feel faint (sign of low blood pressure), agitated or sick.

If you forget to have Desferal

If you forget to have Desferal or miss one of your appointments, tell your doctor, nurse or pharmacist straight away. Do not have a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Desferal can cause side effects, although not everybody gets them.

Your urine may turn a reddish-brown colour. This is because the extra iron that sticks to Desferal and passes into your urine, is reddish-brown in colour. This is usually nothing to worry about. If you are worried you should talk to your doctor, pharmacist or nurse.

Stop having Desferal and tell your doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- bronchospasm with wheezing or coughing and difficulty in breathing
- feeling faint (you may have low blood pressure), have a rash, or experience itching or facial swelling. These might be the result of an allergic reaction which is very rare (likely to affect fewer than 1 in 10, 000 patients)
- problems with your sight or hearing
- fits.

Stop having Desferal and tell your doctor straight away, if you notice any of the serious side effects above.

Tell your doctor straight away – important information if you get an infection while you are having Desferal

If you start to feel feverish with a sore throat, stomach pains or diarrhoea while you are taking Desferal, you must tell your doctor straight away. This is because people who have iron on aluminium overload are more at risk of certain types of infection. If you get an infection your doctor may want you to do some tests and give you some medicines to treat the infection. You may also have to stop using Desferal until any infections clear up.

Other side effects include:

Talk to your doctor, nurse or pharmacist if you get any side effects.

Very common: may affect more than 1 in 10 people
- pain, swelling, redness, a rash, itching or scabbing at the injection site
- aching muscles or joints in the arms or legs.

Common: may affect up to 1 in 10 people
- headache
- itchy rash
- feeling sick
- high temperature
- changes in bones or slowing of growth rate (especially in children under 3).

Uncommon: may affect up to 1 in 100 people
- asthma
- being sick
- stomach pain
- blisters and a burning feeling at the injection site.

Rare: may affect up to 1 in 1,000 people
- fungal infections.

Very rare: may affect up to 1 in 10,000 people
- dizziness
- diarrhoea
- kidney problems
- changes in the blood (shown up on blood tests)
- tingling, pins and needles, pricking or numbness of the skin.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desferal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the outside of the pack.
- Do not store above 25 °C. Reconstituted solution: Single use only.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and further information

What Desferal contains
- The active substance is desferoxamine mesilate. Each vial contains 500 mg of desferoxamine mesilate in a dry powder form.

What Desferal looks like and contents of the pack

Desferal is a white to off-white powder for solution for injection or a powder for concentrate for solution for infusion.

It will be dissolved in "water for injections" to make a clear colourless to slightly-yellow solution.

Desferal vials come in packs of ten 500 mg vials. The vials are Type 1 Ph. Eur. Clear, colourless 7.5 mg glass vials with bromobutyl rubber closure and an AL/pp flip- off cap.

Manufacturer:
Novartis Pharma GmbH
Roonstrasse 25
90429 Nürnberg
Germany

Marketing Authorisation Holder:
Novartis Ireland Limited
Vista Building,
Elm Park, Merrion Road,
Ballsbridge, Dublin 4, Ireland.

This leaflet was revised in 12/2020.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Storage condition of the reconstituted solution
Reconstituted solution: Single use only. Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at 2–8° C

From a microbiological point of view, the product should be used immediately after reconstitution (commencement of treatment within 3 hours) and discard any remaining solution after use.

If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2–8° C when reconstitution has taken place in controlled and validated aseptic conditions.

How to prepare and administer Desferal 500mg Vials
Before parenteral administration (subcutaneous and intravenous), the preparation must be diluted with 5mL of water for injections Ph. Eur. to form a 95 mg/mL solution. The 95 mg/mL Desferal solution can be further diluted with routinely employed infusion solutions (NaCl 0.9%, glucose 5%, Ringer's solution Ringer's-lactate solution and peritoneal dialysis solutions such as Dianeal 137 Glucose 2.27%, DIANEAL PD4 Glucose 2.27% and CAPD/DPCA 2 Glucose 1.5%).

When administered intramuscularly, where a higher concentration may be necessary, the preparation must be diluted with 2ml of water for injections Ph. Eur. to form a 213 mg/mL solution.

Preparation of powder for solution for injection is given in Tables 1 and 2 for subcutaneous, intraveneous and intramuscular administrations, respectively. After the appropriate amount of water for injection is injected into the vial containing Desferal powder, the vial is shaken well. Only clear and colorless to slightly yellowish solutions should be used.

Table 1: Preparation for subcutaneous and intravenous administrations

RECONSTITUTE DESFERAL WITH STERILE WATER FOR INJECTION

Vial Size	Amount of Sterile Water for Injection Required for Reconstitution	Total Drug Content after Reconstitution	Final Concentration per mL after Reconstitution
500 mg	5 mL	500 mg/5.3 mL	95 mg/mL

Table 2: Preparation for intramuscular administration

RECONSTITUTE DESFERAL WITH STERILE WATER FOR INJECTION			
Vial Size	Amount of Sterile Water for Injection Required for Reconstitution	Total Drug Content after Reconstitution	Final Concentration per mL after Reconstitution
500 mg	2 mL	500 mg/2.35 mL	213 mg/mL

Please see Summary of Product Characteristics for further information.