PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

DESFERAL 0.5 GRAM

Powder for preparation of a solution for injection/infusion

Active ingredient

Each vial contains 0.5 gram deferoxamine mesylate.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It might harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Desferal 0.5 gram is intended for:

- treatment of chronic iron overload.
- treatment of chronic aluminum overload in patients with kidney failure treated with dialysis.
- treatment of acute iron poisoning.
- a test to diagnose iron overload.

Therapeutic group: chelating agents.

Desferal 0.5 gram is used to clear excess iron or aluminum from the body. This may be necessary in patients with certain types of anemia, such as thalassemia, who need frequent blood transfusions (which may lead to excess iron build-up) and in patients with severe kidney disturbances who need to regularly undergo dialysis treatments (which may lead to excess aluminum build-up).

In addition, Desferal 0.5 gram can be used to treat acute iron poisoning and to check for iron overload.

Desferal 0.5 gram traps and clears excess iron or aluminum, which is then excreted via the urine and stools.

Desferal 0.5 gram can be used in adults, adolescents and children.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
you are sensitive (allergic) to the active ingredient (deferoxamine).

Special warnings regarding the use of the medicine

Before treatment with Desferal 0.5 gram, tell the doctor if:

- you suffer from a kidney disturbance.
- you suffer from any other ailments or allergies.
- you are taking other medicines (including prescription medicines) or use other topical (applied) medicines.

Report to the doctor immediately if any of the following symptoms develop during the course of treatment with Desferal 0.5 gram:

- high fever, sore throat, acute diarrhea or generalized discomfort (signs of a fungal or bacterial infection).
- severe reduction in urinary output (a sign of kidney disturbances).
- vision or hearing disturbances.
- dizziness, lightheadedness (signs of low blood pressure), shortness of breath; these effects may occur if the medicine is given via an intravenous infusion that is too fast.
- heart function disturbances – a possible symptom in patients who use Desferal 0.5 gram and high dosages of vitamin C. If the doctor prescribes you vitamin C supplements, only take them at the dosage prescribed by the doctor and at least one month after you started regular use of Desferal 0.5 gram. For adults, do not exceed a daily dose of 200 mg vitamin C, divided into doses. For children under 10 years of age, 50 mg vitamin C per day is an adequate dose; for older children, the dose is generally 100 mg.

Only use Desferal at the dosage recommended by your doctor. A high dosage may lead to a local injection site reaction or affect hearing, vision, lung or nervous system function.

In children, it can slow growth. Report to the doctor if the child's growth is slower than normal during the course of treatment with Desferal 0.5 gram.

Tests and follow-up

You may have to perform certain blood and urine tests before and during the course of treatment.

For patients with iron overload, iron (ferritin) levels in the body will be checked to assess the efficacy of Desferal 0.5 gram. In addition, vision and hearing must be checked. In children, growth and body weight will be checked regularly.

The doctor will consider these tests when determining the most appropriate treatment dosage.

In addition, if you take vitamin C during the course of treatment with Desferal 0.5 gram, the doctor will check heart function.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- medicines that contain prochlorperazine (used to treat neurological disturbances).
- vitamin C.
- gallium-67 or gallium-68 (radioactive medicines for diagnostic imaging).

Pregnancy and breastfeeding

Women must report to the doctor if they are pregnant or are planning to become pregnant.

Do not use Desferal 0.5 gram during pregnancy and breastfeeding, unless the doctor explicitly recommendeds it.

Breastfeeding during the course of treatment with Desferal 0.5 gram is not recommended. Tell the doctor if you are breastfeeding. If you have questions about this, refer to the doctor.

Driving and using machinery

This medicine may affect responses, ability to drive and ability to use tools and machinery.

Desferal 0.5 gram may affect hearing and vision, cause dizziness or have other effects on nervous system functions. If you develop any of these symptoms, do not drive or use tools or machinery until you feel better.

Children should be warned about riding bicycles or playing near the street, and the like.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only. The doctor may increase or decrease your dosage in accordance with your reaction to the treatment.

Desferal 0.5 gram is intended for administration as a solution in water for injection. Dissolve the Desferal Powder in water for injection given to you by the doctor or pharmacist.

At the recommended concentration of 95 mg/ml (for subcutaneous use), the prepared solution is clear and colorless to slightly yellowish. Only clear solutions can be used. Discard milky or cloudy solutions.

Treatment of chronic iron overload

The doctor will adjust the dosage to your specific condition.

Desferal 0.5 gram can be given in three different ways: in a slow subcutaneous infusion (subcutaneous infusion via an infusion pump), by injection into the muscle or infusion into a vein.

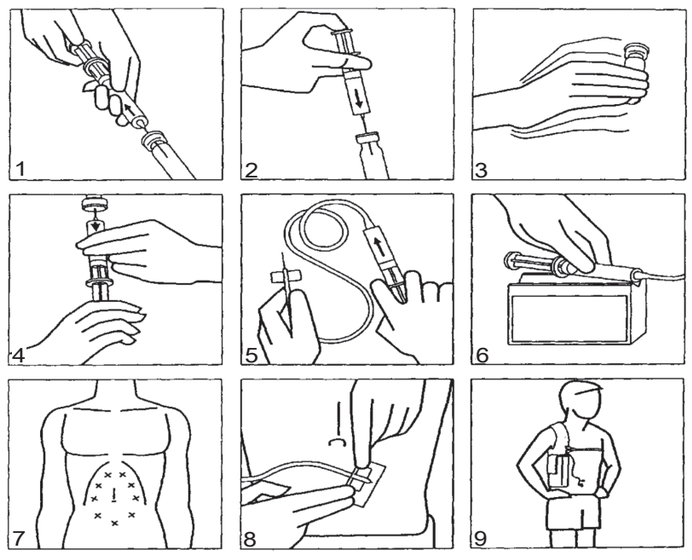
The doctor or nurse will prepare the injection for you or teach you how to do it on your own. The slow subcutaneous infusion of Desferal 0.5 gram for 8-12 hours (e.g., during the night) via a lightweight, portable infusion pump is suitable for long-term treatment in patients with iron overload.

Desferal 0.5 gram is usually given via a pump 5 to 7 times a week.

Assemble the pump carefully and under extremely clean conditions.

Please follow the following instructions and related illustrations to prepare the solution and infuse the solution under the skin.

1. Draw the water for injection into a syringe (see illustration 1).
2. Clean the rubber stopper of the Desferal 0.5 gram vial with alcohol and then inject the contents of the syringe (see illustration 2) into the vial.
3. Shake the vial gently to dissolve the powder (see illustration 3).
4. Draw the resulting solution into the syringe (see illustration 4).
5. Attach one end of the extension tube to the syringe, connect the other end of the extension tube to the butterfly needle and then fill the empty space in the tube with the solution in the syringe (see illustration 5).
6. Place the syringe in the infusion pump (see illustration 6).
7. To give the infusion, insert the butterfly needle under the skin (subcutaneously). The chosen site can be on the abdomen, arm or thigh (see illustration 7). It is very important to first thoroughly disinfect the skin with alcohol. Then, insert the needle up to the wings, into the fold of skin you formed with your free hand. The tip of the needle should move freely when the needle is waggled. If it does not move freely, the tip of the needle may be too close to the surface of the skin. Try again at a new site after disinfecting it with alcohol.
8. When the tip of the needle moves freely under the skin, fixed it in place with a plaster bandage (see illustration 8).
9. Patients usually carry the pump on their body, using a belt or shoulder pouch. Many patients find overnight use of the pump most convenient (see illustration 9).



Treatment of chronic aluminum overload:

- Desferal 0.5 gram is generally give once a week, in a slow intravenous infusion or over the last 60 minutes of dialysis or 5 hours before dialysis treatment, depending on the aluminum levels in the blood.
- If you are receiving continuous ambulatory peritoneal dialysis (CAPD) or continuous cyclic peritoneal dialysis (CCPD), you should take the Desferal dose before the last exchange of that day.
- The doctor will arrange for you tests that will determine how long you will be treated, and whether the Desferal 0.5 gram dose should be changed.

Iron overload test

If you have to undergo an iron overload test, you will receive an intramuscular injection of Desferal 0.5 gram and will be asked to collect urine for 6 hours to determine the iron content in the urine.

Do not exceed the recommended dose, since it may lead to side effects.

Adhere to the treatment regimen as recommended by the doctor.

Do not stop treatment with Desferal 0.5 gram without being instructed to do so by the doctor.

If you missed a dose of Desferal 0.5 gram or accidentally took too much Desferal 0.5 gram, consult the doctor or refer immediately to a hospital. You may need medical treatment.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Desferal 0.5 gram may cause side effects in some users. Most of the side effects are mild to moderate and generally disappear after a few days or weeks of treatment.

Very common side effects (effects that occur in more than one in ten users):

- Muscle and joint pains, injection site reactions such as pain, swelling, redness, itching, burning or crusting or blistering.

Common side effects (effects that occur in 1-10 in 100 users):

The following side effects may be serious. If you experience any of them, consult the doctor immediately:

- Headache, fever, urticaria, nausea.
- Children often experience delayed growth and bone changes.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

The following side effects may be serious. If you experience any of them, consult the doctor immediately:

- Hearing disturbances, such as ringing or noise in the ears, hearing loss.
- Asthma.
- Vomiting, abdominal pains.

Rare side effects (effects that occur in 1-10 in 10,000 users):

The following side effects may be serious. If you experience any of them, consult the doctor immediately:

- Infections (fungal or bacterial) which may lead to high fever, shortness of breath, acute diarrhea, abdominal pain, generalized discomfort or sore throat.
- Vision disturbances, such as blurred vision, abnormal color vision, night blindness, seeing black spots, vision loss, cloudy lens, visual field disturbances or reduced visual acuity.

Very rare side effects (effects that occur in less than one in 10,000 users):

The following side effects may be serious. If you experience any of them, consult the doctor immediately:

- Gastrointestinal inflammation.
- Blood and circulation disturbances, such as dizziness, lightheadedness (signs of low blood pressure which may occur when the medicine is given too quickly), hematomas or unusual bleeding (signs of reduced platelet count).
- Allergic reactions and respiratory problems, such as rash, itching, urticaria, breathing and swallowing problems, swelling (primarily in the face and throat), pressure in the chest with wheezing or cough, shortness of breath, breathing difficulty, reduced blood pressure.
- Nervous system disturbances, such as convulsions (primarily in dialysis patients), numbness and prickling in the fingers and toes.
- Rash.
- Diarrhea.

Side effects whose frequency has not been determined:

The following side effects may be serious. If you experience any of them, consult the doctor immediately:

- Kidney problems, such as severe reduction in urine output (sign of kidney failure).
- Seizures.

Additional possible side effects:

- Muscle cramps, diarrhea, urine discoloration, reduced blood calcium level and worsening of hyperparathyroidism (increased parathyroid hormone production) in patients receiving treatment for aluminum overload.
- The color of the urine may turn reddish-brown due to higher iron level in the urine. This is usually not a reason for concern, but if you are worried, please speak with the doctor.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" that can be found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by clicking on the link: https://sideeffects.health.gov.il/

In addition, they can be reported to Novartis via the following email address:
safetydesk.israel@novartis.com

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C. Protect from light.

One vial is for single use.

After reconstituting (dissolving) the preparation, it should be used immediately (start use within 3 hours).

6. FURTHER INFORMATION

What the medicine looks like and contents of the package:

Each package contains 10 vials that contain 5 grams of powder for reconstitution.

Registration Holder and its address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 107-07-21532

Revised in December 2024 according to MOH guidelines.

DES APL 19DEC24 V1

הוראות הכנה והזרקה לצוות הרפואי:

تعليمات التحضير والحقن للطاقم الطبي:

Preparation and injection instructions for healthcare professionals:

When administered parenterally (i.v. and s.c.), the drug should preferably be used as a 95 mg/ml solution in water for injection, except for i.m. injection, where a higher concentration may be necessary. Water for injection, 5 ml, is injected into the vial containing 500 mg Desferal powder. If there is no option other than intramuscular injection, a 213 mg/ml solution in water for injection should preferably be used. Water for injection, 2 ml, is injected into the vial containing 500 mg Desferal powder and the vial is shaken thoroughly (see section 3 “How should you use the medicine?”). Only clear and colorless to slightly yellowish solutions may be used.

The 95 mg/ml Desferal solution after reconstitution may be further diluted with standard infusion solutions (0.9% NaCl, 5% glucose, Ringer’s solution, Ringer’s lactate solution, peritoneal dialysis solutions such as Dianeal PD4 [2.27% glucose] and CAPD/DPCA 2 [1.5% glucose]).

For the Desferal infusion test and the treatment of chronic aluminum overload, the 5.3 ml Desferal solution in the 500 mg vial is an adequate dose (5 mg/kg) for a patient with 100 kg body weight (see section 3 “How should you use the medicine?”). The appropriate amount of Desferal solution for the patient body weignt is withdrawn from the vial and added to 150 ml 0.9% saline solution.

The medicinal product may only be mixed with the solutions specified above.

Administration by means of a portable infusion pump is appropriate for the long-term treatment of patients with iron overload. Instructions for preparation of the solution and for administration are as follows:

1. Draw the water for injection into a syringe.
2. Clean the rubber stopper of the Desferal vial with alcohol, and inject the contents of the syringe (cf. 1) into the vial.
3. Shake the vial vigorously to dissolve the powder.
4. Draw the resulting solution into the syringe.
5. Attach one end of the extension tube to the syringe, connect the other end to the butterfly-type needle, and fill the empty space in the tube with the solution in the syringe.
6. Place the syringe in the infusion pump.
7. To give the infusion, insert the butterfly-type needle under the skin (subcutaneously). The site chosen can be on the abdomen, arm or thigh. Before inserting the needle, the site must first be thoroughly disinfected with alcohol. Insert the needle firmly up to the wings into a fold of skin formed by your free hand. The tip of the needle should move freely when the needle is waggled. If this is not the case, the tip of the needle may be too close to the surface of the skin. Insertion should then be reattempted at a new site after disinfection with alcohol.
8. When the needle is correctly positioned (i.e., moves freely), it should be fixed in place using adhesive tape.

Patients usually carry the pump on their body using a belt or shoulder strap. Many patients find overnight use most convenient.