

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

The dispensing of this medicine
requires a doctor's prescription

Read this package insert carefully in
its entirety before using this medicine

DESFERAL® 0.5 g

Powder for solution for intramuscular (I.M.)
injection.

Powder for solution for intravenous (I.V.),
subcutaneous (S.C.) infusion.

Composition:

Each vial contains:
Deferoxamine mesylate 0.5 g/vial

Inactive ingredients: None.

Therapeutic group: Chelating agent.

Therapeutic activity:

- Treatment of chronic iron overload.
- Treatment of chronic aluminium overload in patients with kidney insufficiency under dialysis.
- Treatment of acute iron poisoning.
- Diagnostic test for iron overload.

Desferal traps excess iron or aluminium, which is then excreted through the urine and faeces.

Desferal can be used to treat adults, adolescents and children.

When should the preparation not be used?

Do not use this medicine if you are allergic (hypersensitive) to **Desferal** (deferoxamine) except where desensitization of the patient makes **Desferal** treatment possible.

Do not use this medicine without consulting a doctor before starting treatment:

If you are pregnant, planning to become pregnant, or breast-feeding. In general, **Desferal** should not be used during pregnancy or breast-feeding unless the doctor advises treatment. The doctor will discuss with you the potential risk of using **Desferal** during pregnancy. Breast-feeding is not recommended during treatment with **Desferal**. Tell your doctor if you are breast-feeding.

If you think you may be allergic to **Desferal**.

Inform the doctor before using **Desferal** if you have any kidney disorders or if you are receiving dialysis.

If you are suffering, or have suffered in the past, from impaired function of the heart, nervous system or from kidney/urinary tract problems.

If you suffer from hyperparathyroidism or thalassemia.

How will this medicine affect your daily life?

Desferal may impair vision or hearing, cause dizziness or other nervous system disturbances. If you experience such effects, avoid activities such as driving a car and operating dangerous tools and heavy machinery until you know how the medicine affects you. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like.

Warnings:

Use of this medicine may cause blurred vision or hearing problems. You should test your eyesight and hearing since **Desferal** can affect your vision and your hearing. These tests should be done every 3 months.

You should take certain blood and urine tests before and during treatment with **Desferal**.

For patients with iron overload, levels of iron (ferritin) in your body will be monitored to see how **Desferal** is working.

In children under the age of 3 years, high doses of **Desferal** may affect growth. Therefore, growth and body weight should be checked at regular intervals (every 3 months). The doctor will take these tests into consideration when deciding on the dose of **Desferal** most suitable for you.

If you are taking vitamin C during treatment with **Desferal**: your doctor should monitor your cardiac function during such combined treatment.

Vitamin C supplements should not be given to patients with cardiac failure.

Too rapid infusion of **Desferal** into a vein may lead to hypotension and shock (e.g., flushing, tachycardia, urticaria, collapse).

If you have any questions about how **Desferal** works or why this medicine has been prescribed for you, ask your doctor.

• Heart disorders such as blushing, accelerated heart beat, collapse, are possible symptoms 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 the vitamin. You should take Vitamin C only in the dosage prescribed by the doctor. Do not exceed a daily dose of 200 mg in divided doses. For children under 10 years of age the dosage is usually 50 mg/day, and for children above 10 years of age - 100 mg/day.

• Tell your doctor if you notice that your **Desferal**-treated child has slower than normal growth.

In patients with encephalopathy due to aluminium overload, high doses of **Desferal** may exacerbate neurologic dysfunction and cause convulsions, apparently as a result of an acute increase of aluminium in the blood circulation.

Treatment of aluminium overload can lead to decreased calcium in the blood and aggravation of hyperparathyroidism.

Patients who self-inject the medicine must undergo thorough strict instruction in the injection technique.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions:

If you are taking another drug concomitantly, including non-prescription drugs and nutritional supplements, or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: prochlorperazine (a phenothiazine derivative); vitamin C (doses higher than 200 mg per day during treatment with **Desferal**). Do not take more than 200 mg of vitamin C per day

(see "Warnings"), gallium-67 a medicine given before imaging (scanning) and used in diagnosis of certain diseases. It may be necessary to change the dosage or stop taking one of the medicines.

Side effects:

As with all medicines, patients treated with **Desferal** may experience side effects, although not everybody gets them. Most of these side effects are mild to moderate and will generally disappear after a few days to weeks from the beginning of treatment. Please do not be alarmed by this list of possible side effects. You may not experience any of them.

Side effects may occur with certain frequencies, which are defined as follows:

Very common side effects may affect more than 10 out of every 100 patients.

Common side effects may affect between 1 and 10 patients out of every 100 patients.

Uncommon side effects may affect between 1 and 10 patients out of every 1,000 patients.

Rare side effects may affect between 1 and 10 patients out of every 10,000 patients.

Very rare side effects may affect fewer than 1 out of every 10,000 patients.

Unknown frequency - frequency of the side effects cannot be determined reliably.

Very common side effects: injection site reactions, such as pain, swelling, reddening, itching of the skin, scab, crust formation, small blisters, burning; aching joints or muscles.

Common side effects: headache, itchy rash, nausea, fever; reduced growth rate, bones disorders.

Uncommon side effects: vomiting and abdominal pain.

Very rare side effects: diarrhoea, skin rash, sensation of numbness or tingling in fingers and toes.

Side effects whose frequency is unknown: muscle spasms.

Please note your urine may turn reddish-brown during treatment with **Desferal**. This is because it contains more iron. These changes are not a cause for concern, but if you are worried, talk to your doctor or nurse.

If you experience any other side effects not mentioned in this leaflet, inform the doctor or the pharmacist.

Side effects that require special attention:

Stop taking the medicine and tell your doctor straight away if you experience any of the following symptoms:

- Bronchospasm (breathlessness) or tightness of chest with wheezing or coughing and difficulty in breathing.
- If you feel faint (you probably have low blood pressure), have a rash, itching, difficulty breathing or facial and throat swelling. This may occur due to sensitivity to the medicine (a rare effect).
- Severe decrease in urine output (sign of kidney problem) or convulsions (occur mainly in patients on dialysis).
- Visual and hearing impairments.

Tell your doctor right away, if you experience any of the following symptoms during treatment with Desferal:

- If you develop an infection: high fever, sore throat, shortness of breath, abdominal pain, acute diarrhoea or general discomfort (signs of fungal or bacterial infections). In such case, the doctor may want you to do some tests and treat the infection. You may also have to stop using **Desferal** until the infection clears up.
- Dizziness, light-headedness (signs of low blood pressure), blushing, accelerated heart beat, collapse and urticaria that can occur if the drug is given too rapidly by infusion into a vein.

Uncommon side effects: disturbances of hearing such as ringing or noise in the ears, hearing loss.

Rare side effects: vision disturbances e.g., blurred vision, loss of vision, abnormal colour vision, night blindness, black spots in the field 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 diarrhoea, abdominal pain, general discomfort or sore throat; dizziness (a sign of low blood pressure that can occur when the drug is given too rapidly).

Very rare side effects: breathlessness due to lung disorders; unusual bleeding/bruising (signs that levels of blood platelets are low); fever, sore throat or mouth sores due to infections (signs that levels of white blood cells are low); rash, itching, hives (allergic skin reaction), difficulty breathing or swallowing; feeling of tightness in chest accompanied by wheezing or coughing, swelling mainly of the face and throat (signs of severe allergic reaction or asthma); disturbances of the nervous system.

Side effects whose frequency is unknown: severe decrease in urine output (sign of kidney problem), convulsions (mainly in patients on dialysis).

Abnormal liver or kidney function test results, spasms, hypocalcemia and aggravation of hyperparathyroidism in patients treated for aluminium overload.

If you experience one or more of these effects, stop treatment and contact the doctor immediately!

Adverse reactions and drug interactions in children:

Reduced growth rate (less common): contact your doctor as soon as possible if you notice such an effect!

Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child! See above for details of special side effects and drug interactions.

Dosage:

Dosage is according to doctor's instructions only. Do not exceed the recommended dosage.

This medicine is to be used at specific time intervals as determined by the attending doctor. If you forget to take this medicine at the specified time, contact your doctor immediately.

If you used a higher dose by mistake, contact your doctor immediately.

Directions for use:

Before using Desferal at home, you should get guidance from the medical team regarding preparation of solution and method of administration.

Follow your doctor's instructions.

Do not exceed the recommended dose since it can increase and worsen side effects.

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 increase or decrease your dose.

For subcutaneous administration of Desferal:

Desferal is intended to be used as a solution in water for injection. Dissolve **Desferal** powder in the water for injection that your pharmacist has given you, at the recommended concentration of 95

mg/ml. Afterwards it should be shaken well. The made-up solution is colourless or slightly yellowish. The solution should be clear. Do not use a cloudy solution.

One vial is for a single use only. After the preparation is made up, use it immediately (i.e. start of treatment within 3 hours).

Treatment of chronic iron overload:

The doctor will adjust the dose to your particular condition.

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.

The doctor or nurse can prepare the 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 preparation the solution and infusing it under the skin:

1. Draw the water for injection into a syringe (see fig. 1).
2. After cleaning the rubber stopper of the **Desferal** vial with alcohol, inject the content of the syringe into the vial (see fig. 2).
3. Shake the vial thoroughly to dissolve the powder (see fig. 3).
4. Draw the obtained solution into the syringe (see fig. 4).
5. Attach the extension tube to the butterfly-type needle, and then fill the empty space in the tube with the solution in the syringe (see fig. 5).
6. Place the syringe into the infusion pump (see fig. 6).

7. For infusion you may insert the butterfly-type needle under the skin of the abdomen, the arm, the upper leg or the thigh (see fig. 7).

It is very important to first clean the skin very thoroughly with alcohol. Then 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 wiggled. If it does not 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. Fix the needle and tape it down with a plaster (see fig. 8).

9. Patients usually wear the pump on the body using a belt or shoulder holster. Many patients consider overnight use the most convenient (see fig. 9).

Treatment of chronic aluminium overload:

• **Desferal** is usually given once a week, by slow infusion into a vein or during the last 60 minutes of a dialysis session, or 5 hours prior to 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.

• 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.

Test to detect iron overload:

If you have to undergo testing for iron overload, you will be given usually an intramuscular injection of **Desferal** and will be asked to collect your urine for 6 hours. The urine will then be checked for iron.

How can you contribute to the success of the treatment?

Make sure you use this medicine regularly and exactly as your doctor tells you. This will help you to get the best results and reduce the risk of side effects.

If you are in doubt about your treatment, refer to your doctor. If you have any questions about how long to take **Desferal**, ask your doctor or pharmacist.

Do not stop using **Desferal** unless your doctor tells you to. If you stop using it, the excess iron will no longer be removed from your body.

Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

Do not take 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 heart beat, gastrointestinal disturbances (nausea), severe decrease in urine output (sign of a kidney disorder), nervous system disorders (e.g., agitation, inability to speak, headache), breathlessness (sign of a lung disorder), visual and hearing disorders.

If you have used an overdose, or if a child or any other person has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Medical treatment may be necessary.

Do not induce vomiting unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.

Do not give this medicine to your relatives, neighbours or acquaintances.

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

Storage:

Do not store above 25°C.

One vial is for a single use only.

After reconstitution, use the medicine immediately (i.e. start use within 3 hours).

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Store in the original package.

Do not store different medications in the same package.

Do not use if the package is damaged.

License number: 107 07 21532

Manufacturer:

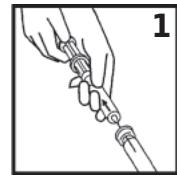
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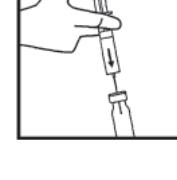
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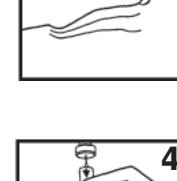
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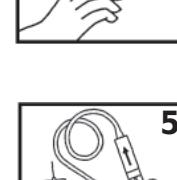
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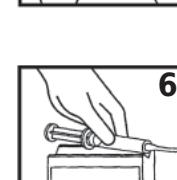
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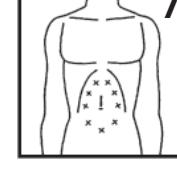
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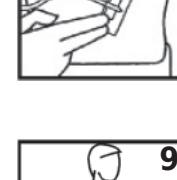
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