

Desferal®

desferrioxamine mesylate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Desferal.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au

Those updates may contain important information about the medicine and its use of which you should be aware.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Desferal is used for

Desferal can be used:

- to treat acute iron poisoning
- to treat chronic iron overload

Iron can build up in your body if you take too many iron preparations or if

you have a type of anaemia that requires a lot of blood transfusions, such as thalassaemia (also called Mediterranean anaemia) or sickle cell anaemia. Desferal is useful in these cases to reduce iron buildup in the liver and prevent liver damage.

Desferal belongs to a group of medicines called metal chelators.

It is an "iron carrier." If you have too much iron in your body, Desferal attaches itself to the extra iron and gets rid of it through the urine and bowel motions.

Ask your doctor if you have any questions about why Desferal has been prescribed for you.

Your doctor may have prescribed it for another reason.

Desferal can be used to treat both adults and children, but children under 3 years of age may not respond as well as older people. If you are unsure whether your child should have Desferal, your doctor can provide more information.

This medicine is only available with a doctor's prescription. It is not habit-forming.

Before you have Desferal

When you must not have it

Do not have Desferal if you have had an allergic reaction to desferrioxamine, the active ingredient in Desferal.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing;

swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

It may be possible to have a desensitisation treatment to overcome your allergy to Desferal. If the desensitisation treatment is successful, you will be able to have Desferal again. Be sure to discuss this with your doctor.

Do not have Desferal after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to have it

Tell your doctor if you have any of the following health problems/ medical conditions:

- severe kidney disease
- heart disease
- problems with your eyesight
- problems with your hearing

Tell your doctor if you are pregnant or breast-feeding.

Desferal may affect your baby if you have it while you are pregnant, especially in the first 3 months. It is not known if the active ingredient of Desferal passes into the breast milk.

If it is necessary for you to have this medicine, your doctor will discuss with you the benefits and risks of having it during pregnancy or while breast-feeding.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell him/her before you start Desferal.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Desferal may interfere with each other. These include:

- Vitamin C (ascorbic acid)
- prochlorperazine, a medicine used to treat nausea (feeling sick), vomiting and vertigo
- methyldopa, a medicine used to treat high blood pressure
- Gallium-67, a medicine used in some radiology procedures

Other medicines may be affected by Desferal or they may affect how well it works. You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while having Desferal.

How Desferal is given

Desferal is usually given by a slow infusion under the skin using a portable light-weight infusion pump. It can also be given by infusion (drip) into a vein or by injection into a muscle.

You will usually be in hospital for the first part of your treatment. If you need treatment over a long period, you will probably use an infusion pump at home. The pump will be set up for you before you leave hospital and you will be taught how to use it.

How much you need

To treat acute iron poisoning: the dose of Desferal you need will

depend on how much extra iron you have in your body.

To treat chronic iron overload: your doctor will decide how much you need and how often the injections will be given, depending on your particular condition and how well you respond to treatment. For most adults, daily doses of 20 to 60 mg per kilogram of body weight are enough.

If you must keep having Desferal to control your iron levels, your doctor may prescribe Vitamin C (ascorbic acid) to help Desferal work better. Vitamin C can be started after at least one month of regular treatment with Desferal. The maximum daily dose for an adult is 200 mg. Children usually take 50 mg to 100 mg each day, depending on age.

Using an infusion pump

Carefully follow all directions given to you by your doctor, pharmacist or nurse.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions you have been given, ask your doctor, pharmacist or nurse for help.

Each vial of Desferal contains the medicine in a dry powder form. The powder must be dissolved in sterile water to form a liquid, which is injected under the skin using the infusion pump. Each dose of Desferal must be carefully prepared under very clean conditions.

Be careful to add the correct amount of sterile water to the vial of Desferal and use the exact dose recommended by your doctor.

Higher doses or concentrations of medicine can cause skin reactions at the injection site, or could affect your sight, hearing, lungs, nervous system or growth rate. See below for other possible effects after taking too much Desferal (overdose).

Use the liquid in the vial as soon as possible. If you have to store it,

keep it in the refrigerator and use it within 24 hours.

To prepare a dose of Desferal, follow these steps:

1. Wash your hands thoroughly and dry them on a clean towel.
2. Unwrap a sterile syringe and attach a new sterile needle to it.
3. Break the top off an ampoule of sterile Water for Injections.
4. Draw up the right amount of water into the syringe. For the 500 mg strength, you need to use 5 mL of water to dissolve the powder. For the 2 gram strength, you need to use 20 mL of water to dissolve the powder.
5. Clean the rubber stopper of the Desferal vial with an alcohol wipe.
6. Inject the water from the syringe through the stopper into the vial.
7. Shake the vial well to dissolve the dry powder. It will become a clear, colourless or slightly yellowish liquid. Do not use it if the liquid is cloudy or you can't see through it.
8. Clean the stopper of the vial again with an alcohol wipe and draw the liquid from the vial back into the syringe.
9. Remove the needle from the syringe. Dispose of the needle carefully where it cannot injure you or other people.
10. Follow the instructions given to you by your hospital or the pump manufacturer on how to set up the pump, remove air from the line and inject the dose.

The pump can be carried on a belt or in a shoulder holster so that you can move about while the infusion is going on (e.g. over 8-12 hours). The pump can also be set up to run overnight if this is more convenient.

If your doctor decides that another method of giving Desferal is better for you, be sure to ask them to explain what you have to do.

How long your treatment will last

That will depend on how you respond to the treatment. Blood and urine samples will be collected from you to test how well the treatment is working.

If you are being treated for chronic iron buildup, it is very important that you continue your treatment exactly as prescribed. Desferal can improve your life expectancy if you closely follow the treatment prescribed by your doctor.

If you forget to have it

If you have accidentally missed an injection, call your doctor immediately and ask what you should do.

If you have too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have had too much Desferal. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

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 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.

While you are having Desferal

Things you must do

If you develop a high temperature, which may be accompanied by an inflamed painful throat, shortness of breath, abdominal pain or severe diarrhoea or general discomfort during Desferal treatment, tell your doctor immediately.

Desferal may make you prone to certain serious bacterial and fungal infections.

If you become pregnant while having Desferal, tell your doctor immediately.

Your doctor can discuss with you the risks of having it while you are pregnant.

Take Vitamin C (ascorbic acid) only if your doctor has prescribed it for you. Be careful to take the correct amount.

The correct amount of Vitamin C helps Desferal to work properly. But too much Vitamin C may cause unwanted effects on your heart or eyesight.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to do blood and urine tests as well as testing your sight and hearing. Children will also be checked regularly for normal growth and bodyweight. Your doctor will also evaluate your heart function if you take vitamin C while using Desferal.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Desferal.

Tell any other doctor, dentist or pharmacist who treats you that you are having Desferal.

Things you must not do

Do not use Desferal to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are having Desferal until you know how it affects you.

This medicine can cause dizziness or affect hearing and eyesight in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Desferal, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- signs of allergy such as rash, itching or hives all over the skin; difficulty breathing or swallowing; tightness in chest with wheezing or coughing; dizziness, swelling of the face, lips, tongue or other part of the body
- signs of fungal or bacterial infection such as a high

- temperature, which may be accompanied by an inflamed painful throat, shortness of breath, general discomfort, mouth ulcers, abdominal pain or severe diarrhoea
- 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. See also "If you have too much Desferal (overdose)".
 - persistent "flu-like" symptoms such as chills, aching joints, swollen glands, tiredness or lack of energy
 - unusual bleeding or bruising
 - problems with your eyesight such as blurred vision, loss of vision, clouding of the lens of the eye, night blindness, problem with your colour vision, black spots in the vision, visual field defect or decreased sharpness of vision
 - problems with hearing such as ringing or noise in the ears or deafness
 - yellow colour to the skin or eyes
 - sudden decrease in the amount of urine passed or pain when passing urine (sign of kidney disorders)
 - fast, slow or irregular heart beat (pounding, racing, skipping beats)
 - breathlessness due to lung disorder
 - difficult breathing, accompanied by a bluish colour to lips, nails or palms of hands
 - fainting or seizures (fits)
 - Eye swelling and bulging of the eye from the socket
 - headache, dizziness or light headedness
 - disturbances of the nervous system

The above side effects could be serious. You may need urgent medical attention.

Tell your doctor if any of the following happen and they worry you:

- skin reactions at the injection site, such as swelling, redness, itching, burning, pain, formation of scabs, crusts or small blisters. Sometimes these reactions can be accompanied by aching joints or muscles, headache, fever, nausea, vomiting, asthma or abdominal pain.
- weakness or numbness ("pins and needles") in arms or legs
- leg cramps, muscle or joint pain
- muscle spasms
- nausea
- diarrhoea
- reduced growth rate in a child

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

Desferal will cause your urine to turn a reddish-brown colour. This is harmless and shows that the extra iron is being removed from your body in the urine.

After having Desferal

Storage

- Keep your vials in the cardboard carton until it is time to use them.
- Store the vials where the temperature stays below 25°C.

Keep the vials where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Desferal or it has passed its expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Desferal comes in clear glass vials containing the active ingredient, desferrioxamine mesylate, in a dry powder form.

Ingredients

Desferal vials are available in two sizes, containing 500 mg or 2 grams of desferrioxamine mesylate. The vials contain no other ingredients. Water for Injections is sold separately.

Sponsor

Desferal is supplied in Australia by:
NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1-800-671-203

® = Registered trademark

This leaflet was prepared in
November 2011

Australian Registration Number.
Desferal 500 mg vial AUST R 11030
Desferal 2 g vial AUST R 72343