Read all of this leaflet carefully before you start using 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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, see section 4.

What is in this leaflet:
1. What Desferrioxamine Mesilate Powder for Injection is and what it is used for
2. What you need to know before you use Desferrioxamine Mesilate Powder for Injection
3. How to use Desferrioxamine Mesilate Powder for Injection
4. Possible side effects
5. How to store Desferrioxamine Mesilate Powder for Injection
6. Contents of the pack and other information

1. WHAT DESFERRIOXAMINE MESILATE POWDER FOR INJECTION IS AND WHAT IT IS USED FOR
Desferrioxamine mesilate is a binding agent for iron and aluminium. Desferrioxamine mesilate is used to remove excess iron or aluminium from the body in patients with conditions such as iron poisoning, thalassaemia (a hereditary type of anaemia) haemochromatosis (a disorder of iron metabolism) and aluminium overload due to kidney failure. It may also be used to diagnose iron storage disease and some types of chronic anaemias or aluminium overload in some patients.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DESFERRIOXAMINE MESILATE POWDER FOR INJECTION
Do not take Desferrioxamine Mesilate
- if you have shown signs of hypersensitivity (severe allergy) to desferrioxamine mesilate in the past and you have not had treatment to prevent (desensitise you to) this reaction.
Tell your doctor or pharmacist if any of the below applies to you before this medicine is used.

Warnings and precautions
Tell your doctor or pharmacist if any of the below applies to you before this medicine is used
- you have problems with your kidneys or are on dialysis
- you have problems with fits due to high levels of aluminium in the brain
- you have had problems with your sight or hearing during previous treatments with desferrioxamine mesilate
- you are due to have a radiography scan (some radiography scans may be spoilt if desferrioxamine mesilate is used before the scan)
- you have hyperparathyroidism (a condition affecting calcium in the blood)
- this medicine is given to a young child (under the age of 3 years). The doctor may want to monitor the child’s growth regularly as it may be affected by this medicine.
- your doctor has told you that aluminium has resulted in fits. If so, you may be given a dose of clonazepam before you are given desferrioxamine mesilate.
Other medicines and Desferrioxamine mesilate
Special care is needed if you are taking/using other medicines as some could interact with desferrioxamine mesilate, for example:

- vitamin C supplements can help desferrioxamine mesilate remove iron from the body, but may cause heart problems in some patients. Do not take vitamin C supplements during the first month of desferrioxamine treatment
- the side effects of prochlorperazine (a medicine used to treat vertigo, nausea and some types of mental illness) or any medicine of the same family (phenothiazines) may be made worse by desferrioxamine mesilate
- the effectiveness of erythropoietin (a medicine used to increase the number of red blood cells) may be changed once Desferrioxamine mesilate treatment is started

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you should receive this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Desferrioxamine mesilate may cause side effects such as dizziness and problems with vision or hearing. Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

3. HOW TO USE DESFERRIOXAMINE MESILATE POWDER FOR INJECTION

This medicine is given by injection or slow infusion (given over a period of time rather than all in one go). It may be injected into muscle, or infused under the skin, or into a vein or into the abdomen, for patients on peritoneal dialysis. Rapid intravenous infusion may lead to a dangerous decrease in blood pressure and in severe cases to flushing, rapid heart beat, collapse and itchy rash.

Dose

Your doctor will work out the correct dose of Desferrioxamine mesilate for you and how often it must be given.

The dose will depend on your medical condition, your size, your age and how well your kidneys are working. Your doctor will tell how well your kidneys are working using blood or urine samples.

If you are given too much or too little Desferrioxamine Mesilate

This medicine will be used according to your doctor’s instructions. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns. If you have received too much then you may get side effects (see section 4 Possible side effects). Your doctor will be able to take action to reduce the side effects.
4. POSSIBLE SIDE EFFECTS
Like all medicines, desferrioxamine mesilate can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:
- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- fever with a sore throat and abdominal pain or severe diarrhoea
- severe skin infections
- severe breathing difficulties
- blackouts or fits

These are serious side effects. You may need urgent medical attention. Most of these serious side effects are rare.

If any of the following side effects happen, tell your doctor as soon as possible:

Very common (occurs in more than 1 in 10 people)
- a red/brown colouration of the urine often occurs during treatment. This is caused by the presence of removed iron in the urine and is nothing to worry about.
- aching muscles and joints
- leaking of injection fluid into surrounding tissue (infiltration) and dry scabs (eschar) / crust at the site of injection

Common (occurs in between 1 in 100 and 1 in 10 people):
- rash, itching, pain, swelling, burning and hardening of the tissues at the site of the injection, occasionally with fever, chill and feeling generally unwell after the injection
- headache

Uncommon (occurs in between 1 in 1000 and 1 in 100 people):
- hearing loss
- tinnitus (ringing in the ears or head)
- asthma
- blisters and swelling at the site of injection

Rare (occurs in between 1 in 10,000 and 1 in 1000 people):
- blurred vision, impaired or loss of vision, inability to distinguish certain colours (colour blindness), inability to see at night (night blindness), blind spots, changes in the retina, cataracts (cloudy lenses), cloudiness on the front of the eye (or cornea), visual disturbance in which objects appear to be abnormally coloured (chromatopsia)
- dizziness, fits or seizures (mainly in patients on dialysis)
- all-over rash, which may be itchy
- growth problems in children
- nausea, vomiting, abdominal cramps, diarrhoea
- bone pain
- leg cramps
- decreased red blood cells (anaemia) which can make you look pale or cause tiredness, headaches, dizziness or being short of breath when exercising
• decreased platelets (thrombocytopenia) which can make you prone to bleeding or unexpected bruises or nosebleeds
• low blood pressure (lightheadedness, dizziness, faintness) can occur if this medicine is not given correctly (see section 3. How you are given desferrioxamine mesilate)
• abnormal liver function test results
• certain fungal infection of the sinuses, brain and lungs (which can sometimes cause death)

Very rare (occurs in less than 1 in 10,000 people)
• a type of dementia
• numbness or pins and needles
• stomach and gut infections
• a serious condition which causes severe breathing problems called Adult Respiratory Distress Syndrome
• lung infiltration (abnormal presence of fluid in the lung)
• abnormal kidney function test results

Frequency not known (cannot be estimated from the available data):
• decreased white blood cells (leucopenia) which can make you more prone to infections (fever, chills, sore throat or mouth ulcers)
• kidney disease where you pass reduced amounts of urine, and may experience drowsiness, nausea, vomiting and breathlessness
• increase of creatinine in the blood

Your doctor may take blood samples to monitor for changes in your blood cells and liver or kidney function.

Reporting of side effects
If you get any side effects, talk to your doctor or or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DESFERRIOXAMINE MESILATE POWDER FOR INJECTION
Keep out of the sight and reach of children.

Expiry
This medicine must not be used after the expiry date which is stated on the vial label and carton after ‘EXP’. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage
The vials should not be stored above 25°C.
Unused portions of opened vials must not be stored for later use. Prepared injections or infusions should be used immediately, however, if this is not possible they can be stored for up to 48 hours provided they have been prepared in a way to exclude microbial contamination. The prepared injections or infusions should not be refrigerated or frozen.
Visible signs of deterioration
Only clear, pale yellow solutions should be used. Opaque, cloudy or discoloured solutions should be discarded.

Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Desferrioxamine Mesilate contains
The active substance is desferrioxamine mesilate. After reconstitution, each millilitre (ml) of solution contains 100 milligrams (mg) of desferrioxamine mesilate. There are no other ingredients.

What Desferrioxamine Mesilate looks like and contents of the pack
Desferrioxamine Mesilate is a white to cream coloured solid which comes in glass containers called vials.
It may be supplied in packs containing 10 x 500 mg vials or 1 x 2 g vials.

Marketing authorisation holder and manufacturer responsible for batch release in Europe
Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom

Manufacturer
Hospira Australia Pty Ltd,
1-5, 7-23 and 25-39 Lexia Place, Mulgrave,
Victoria 3170,
Australia

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Desferrioxamine Mesilate 500 mg Powder for Injection
Desferrioxamine Mesilate 2 g Powder for Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Heparin is pharmaceutically incompatible with Desferrioxamine mesilate solutions.

Reconstitution and further dilution
Only clear pale yellow desferrioxamine mesilate solutions should be used. Opaque, cloudy or discoloured solutions should be discarded. Unused portions of opened vials must not be stored and should be discarded immediately
The medicinal product should preferably be employed in the form of a 10% solution, e.g. by dissolving the contents of one 500 mg vial in 5 ml of Water for Injections. The 10% desferrioxamine mesilate solution can be diluted with routinely employed infusion solutions (sodium chloride 9 mg/ml (0.9%), glucose 50 mg/ml (5%), or sodium chloride 1.8 mg/ml (0.18%) and glucose 40 mg/ml (4%)), although these should not be used as solvent for the dry substance. Dissolved Desferrioxamine mesilate can also be added to dialysis fluid and given intraperitoneally to patients on continuous ambulatory peritoneal dialysis (CAPD) or continuous cyclic peritoneal dialysis (CCPD).

Following dilution in Water for Injections, chemical and physical in-use stability has been demonstrated for up to 48 hours at 20°C. From a microbiological point of view, however, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and dilution should take place in controlled and validated aseptic conditions.

After dilution, do not refrigerate or freeze.

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