

DBL™ Desferrioxamine Mesylate for Injection BP

desferrioxamine mesilate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Desferrioxamine Mesylate for Injection BP (desferrioxamine mesilate).

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 or pharmacist has weighed the risks of you being given desferrioxamine mesilate against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place. You may need to read it again.

What DBL Desferrioxamine Mesylate for Injection BP is used for

Desferrioxamine mesilate is a binding agent which is used to remove excess iron from the body, thereby reducing damage that excess iron may cause. This may be necessary after poisoning with iron containing medicines or in certain patients with anaemia who receive many blood transfusions.

Desferrioxamine mesilate works by binding with the iron in the

bloodstream. The bound compound can then be removed from the body.

Your doctor may have prescribed desferrioxamine mesilate for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Desferrioxamine mesilate is not addictive.

Desferrioxamine mesilate may be used in children but growth may be affected after prolonged treatment. Ask your doctor for further information.

This medicine is available only with a doctor's prescription.

Before you are given DBL Desferrioxamine Mesylate for Injection BP

When you must not be given it

You should not be given DBL Desferrioxamine Mesylate for Injection BP if you have an allergy to desferrioxamine mesilate or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to desferrioxamine mesilate 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.

Desferrioxamine mesilate must not be given to you if you do not have any excess iron stores. Your doctor will give you tests to confirm your iron levels.

You should not be given DBL Desferrioxamine Mesylate for Injection BP if you are pregnant or intend to become pregnant.

Like most medicines, desferrioxamine mesilate is not recommended for use during pregnancy, especially during the first three months, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not give DBL Desferrioxamine Mesylate for Injection BP to children less than 2 to 3 years of age, unless directed by the child's doctor.

You should not be given DBL Desferrioxamine Mesylate for Injection BP after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

You should not be given DBL Desferrioxamine Mesylate for Injection BP if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using DBL Desferrioxamine Mesylate for Injection BP, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Desferrioxamine mesilate may affect your developing baby if you are given it during pregnancy. If it is necessary for you to be given desferrioxamine mesilate, your doctor or pharmacist will discuss the risks and benefits of you being given it during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

It is not known whether desferrioxamine mesilate passes into breast milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- problems with urination, eg. kidney infection
- kidney disease eg. you are receiving dialysis
- sight or hearing problems
- any heart conditions
- the blood condition "thalassaemia"
- signs of infection, such as fever, chills, stomach pain and/or sore throat
- hyperparathyroidism (a condition resulting in excess calcium in the blood and problems with the bones)

Tell your doctor or pharmacist if you are about to have any scans or x-rays.

Your doctor may recommend that you stop or delay your treatment with DBL Desferrioxamine Mesylate for Injection BP, as it has the potential to interfere with certain scans.

If you have not told your doctor or pharmacist about any of the above, tell them before you start

treatment with DBL Desferrioxamine Mesylate for Injection BP.

If you are being given desferrioxamine mesilate for a prolonged period, you should have sight and hearing tests and a test to confirm blood iron levels before treatment begins.

If your doctor has told you that aluminium has affected your nerves, you may be given the medicine clonazepam before you are given DBL Desferrioxamine Mesylate for Injection BP.

Taking other medicines

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

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

- prochlorperazine; a drug sometimes used for nausea
- any phenothiazines, medicines used mainly to correct chemical imbalance in the brain, which may cause mental illness
- methyldopa; a drug used to treat high blood pressure
- vitamin C (ascorbic acid)
- erythropoietin (used to treat anaemia)

These medicines may be affected by desferrioxamine mesilate or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given desferrioxamine mesilate.

How DBL Desferrioxamine Mesylate for Injection BP is given

How much is given

Your doctor will decide what dose will receive. This depends on your condition and other factors, such as your weight.

How it is given

DBL Desferrioxamine Mesylate for Injection BP may be given as an injection into a muscle, under the skin or as a slow injection into a vein. It may also be given as a slow infusion (eg. as a 'drip') into a vein or under the skin.

If you are on peritoneal dialysis, DBL Desferrioxamine Mesylate for Injection BP may be administered as part of your peritoneal dialysis fluid which is injected into the peritoneum (the membrane that lines the abdominal cavity and forms the outer coating of the abdominal organs).

DBL Desferrioxamine Mesylate for Injection BP should only be given by a doctor, nurse or other trained person.

DBL Desferrioxamine Mesylate for Injection BP is sometimes used for home infusions. If it is to be used at home, you and your carers must be trained in its safe and appropriate use.

If you take too much (overdose)

As desferrioxamine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL Desferrioxamine Mesylate for

Injection BP. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given DBL Desferrioxamine Mesylate for Injection BP

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given desferrioxamine mesilate.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given this medicine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

If you become pregnant while being given desferrioxamine mesilate, tell your doctor or pharmacist.

If you are being given desferrioxamine mesilate for a prolonged period, you should have tests to assess the amount of iron in your urine every few weeks. Sight and hearing tests should be repeated at three-month intervals.

If DBL Desferrioxamine Mesylate for Injection is given to children, it is recommended that three-monthly checks on body weight and height are done by a doctor or nurse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

DBL Desferrioxamine Mesylate for Injection BP should not be used to treat any other complaints unless your doctor or pharmacist tells you so.

Avoid driving or operating machinery until you know how this medicine affects you.

As with some other medicines, desferrioxamine mesilate may cause dizziness, light-headedness and visual or hearing disturbances in some people.

Make sure you know how you react to desferrioxamine mesilate before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Desferrioxamine Mesylate for Injection BP.

Desferrioxamine mesilate helps most people with too much iron in their blood, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- light-headedness or dizziness
- fast heartbeat

- pain, swelling or blisters at the injection site
- hearing problems
- urine changes to orange-rose colour
- black stools
- skin rash, itchiness
- redness or flushing of the skin
- loss of feeling in hands, feet, arms or legs, numbness or tingling (pins and needles).
- aching joints and/or muscles.

These are the more common side effects of desferrioxamine mesilate. Mostly these are mild and short-lived.

Tell your doctor or pharmacist if you notice anything of the following:

- blurred vision or other problems with sight
- nausea, vomiting or diarrhoea
- abdominal or stomach cramps
- problems with urination
- bone pain, leg cramps or involuntary muscle contractions
- headache
- signs of frequent infection, such as fever, chills, sore throat or mouth ulcers
- unexplained or easy bruising, nosebleeds and bleeding gums, prolonged bleeding from cuts
- sudden swelling below or on the skin surface, or around the eyes, lips or throat.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Patients on dialysis may experience personality changes, headache, confusion, paralysis of part or all of the body, stiff neck, abnormal, speech and eye movements.

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- irregular heartbeat, chest pain

- redness or flushing of skin, unusually cold hands and feet
- shortness of breath, rapid breathing
- confusion, dizziness
- blueish colouring of skin
- asthma (bronchospasm or tightness of chest with wheezing or coughing and difficulty in breathing).

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

If you start to feel feverish with a sore throat or stomach pains, or general discomfort or develop shortness of breath while you are taking DBL Desferrioxamine Mesylate for Injection BP, you must seek medical advice immediately.

This is because people who have iron or aluminium overload are more vulnerable to 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. Your doctor may also have you stop using DBL Desferrioxamine Mesylate for Injection BP until any infections clear up.

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

Other side effects not listed above may occur in some patients.

After you have been given DBL Desferrioxamine Mesylate for Injection BP

Storage

DBL Desferrioxamine Mesylate for Injection should be stored in a cool dry place, protected from light, where the temperature stays below 25C.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

DBL Desferrioxamine Mesylate for Injection BP is a white powder. It should be completely dissolved in Water for Injections before use, to produce a clear solution.

Ingredients

Active ingredient:

- Desferrioxamine mesilate

There are no other ingredients.

DBL Desferrioxamine Mesylate for Injection BP does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Pfizer Australia Pty Ltd
 Sydney NSW
 Toll Free Number: 1800 675 229
 www.pfizer.com.au

DBL Desferrioxamine Mesylate for Injection BP is available in the following strengths:

- 500 mg/vial (AUST R 53942).
- 2 g/vial (AUST R 73173).

Date of leaflet preparation - January 2023.

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