

# DBL™ Desferrioxamine Mesylate for Injection BP

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or nurse.

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### **1. Why am I being treated with DBL Desferrioxamine Mesylate for Injection BP?**

DBL Desferrioxamine Mesylate for Injection BP contains the active ingredient desferrioxamine mesilate. It is used to remove excess iron from the body, after poisoning with iron-containing medicines or in certain patients with anaemia who receive many blood transfusions. For more information, see Section [1. Why am I being treated with DBL Desferrioxamine Mesylate for Injection BP?](#) in the full CMI.

## **2. What should I know before treatment with DBL Desferrioxamine Mesylate for BP?**

You should not be started on treatment if you have ever had an allergic reaction to desferrioxamine mesilate, or if tests show that you don't have enough iron stores in your body.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before treatment with DBL Desferrioxamine Mesylate for Injection BP?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with DBL Desferrioxamine Mesylate for Injection BP and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## **4. How is DBL Desferrioxamine Mesylate for Injection BP given?**

Your doctor will decide what dose you will receive and the best way for it to be given. It must only be given by a doctor or nurse (in hospital) or other trained person (at

home). More instructions can be found in Section [4. How is DBL Desferrioxamine Mesylate for Injection BP given?](#) in the full CMI.

## 5. What should I know while I am being treated with DBL Desferrioxamine Mesylate for Injection BP?

### Things you should do

- Call your doctor straight away if you: have visual or hearing disturbances, feel feverish with a sore throat, stomach pains, have difficulty breathing, flushing or itchy skin, are dizzy or lightheaded, or have signs of a urine or kidney infection.
- Remind any doctor, nurse, pharmacist or dentist you visit that you are being given this medicine.
- Tell your doctor if you are due to have any scans, as this medicine may interfere with some scans.
- Ensure you go for any tests recommended by your doctor, especially

	for your eyes and/or hearing or growth in children
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Avoid driving or using any machines or tools as it may cause dizziness, light-headedness and problems with your eyesight and/or hearing.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• No information available.</li> </ul>

For more information, see Section [5. What should I know while I am being treated with DBL Desferrioxamine Mesylate for Injection BP?](#) in the full CMI.

## 6. Are there any side effects?

Light-headedness/dizziness, irregular heartbeat, pain/swelling/blisters at injection site, hearing problems, wee or poo colour changes, skin rash/itchiness/redness/flushing, numbness/tingling/coldness in hands, feet, arms or legs, aching joints/muscles, sight problems, nausea/vomiting, diarrhoea, stomach/abdominal cramps, difficulty urinating/weeing, bone pain, muscle cramps, headache, infection (fever, chills, sore throat, mouth ulcers), unexplained/easy bruising, nose/gum bleeds, prolonged bleeding, sudden swelling of skin, eyes, lips, throat, chest pain, breathing issues, confusion/dizziness, blueish skin colour, fatigue, seizures. Also, for patients

on dialysis: personality changes, paralysis of part/all body, stiff neck, abnormal speech/eye movements.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# DBL™ Desferrioxamine Mesylate for Injection BP

Active ingredient(s): *desferrioxamine mesilate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with DBL Desferrioxamine Mesylate for Injection BP.

**You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using DBL Desferrioxamine Mesylate for Injection BP.**

### Where to find information in this leaflet:

1. Why am I being treated with DBL Desferrioxamine Mesylate for Injection BP?
2. What should I know before I am given DBL Desferrioxamine Mesylate for Injection BP?
3. What if I am taking other medicines?
4. How is DBL Desferrioxamine Mesylate for Injection BP given?
5. What should I know while I am being treated with DBL Desferrioxamine Mesylate for Injection BP?
6. Are there any side effects?
7. Product details

# **1. Why am I being treated with DBL Desferrioxamine Mesylate for Injection BP?**

**DBL Desferrioxamine Mesylate for Injection BP contains the active ingredient desferrioxamine mesilate.**

DBL Desferrioxamine Mesylate for Injection BP 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.

Desferrioxamine mesilate may be used in adults and in children.

## **2. What should I know before I am given DBL Desferrioxamine Mesylate for Injection BP?**

### **Warnings**

#### **You must not be given DBL Desferrioxamine Mesylate for Injection BP if:**

1. you are allergic to desferrioxamine mesilate.

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.

Always check the ingredients to make sure you can use this medicine.

2. you do not have any excess iron stores. Your doctor will give you tests to confirm your iron levels.

Treatment with DBL Desferrioxamine Mesylate for Injection BP may affect growth in children 3 years of age and under. Talk to your doctor regarding risks and benefits of treatment in this age group and any checks that should be done to monitor weight and height.

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

## Check with your doctor if you:

- have or have had any other 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)
- take any medicines for any other condition.

Tell your doctor if 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 are going to be given desferrioxamine mesilate for a prolonged period, you should have sight and hearing tests done before you start your treatment, and also a test to confirm your 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Check with your doctor if you are pregnant or intend to become pregnant.**

DBL Desferrioxamine Mesylate for Injection BP is not recommended during pregnancy, especially during the first three months, unless you and your doctor have discussed the risks and benefits involved.

DBL Desferrioxamine Mesylate for Injection BP may affect your developing baby if you are given it during pregnancy. If it is necessary for you to be given this medicine, your doctor can help you decide whether you should be given it during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

It is not known whether DBL Desferrioxamine Mesylate for Injection BP passes into breast milk; therefore, there is a possibility that the breastfed baby may be affected.

If there is a need to consider using this medicine while you are breastfeeding, your doctor will discuss with you the benefits and risks of you being given it.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with DBL Desferrioxamine Mesylate for Injection BP and affect how it works. These include:**

- prochlorperazine; a medicine used for nausea
- any phenothiazines; medicines used to correct chemical imbalance in the brain and mental illness
- methyldopa; a medicine used to treat high blood pressure
- vitamin C (ascorbic acid)
- erythropoietin (used to treat anaemia)
- gallium-67; an injection given when having some nuclear medicine scans.

These medicines may be affected by DBL Desferrioxamine Mesylate for Injection BP or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use 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 this medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Desferrioxamine Mesylate for Injection BP.**

## **4. How is DBL Desferrioxamine Mesylate for Injection BP given?**

### **How much is given**

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

### **How it is given**

DBL Desferrioxamine Mesylate for Injection BP must be dissolved into a solution using Water for Injections and then 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 dialysis fluid.

It must only be given by a doctor or nurse or another 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 before you can be given the medicine at home.

While DBL Desferrioxamine Mesylate for Injection BP should be used immediately after being dissolved into a solution, if necessary, it can be stored in a refrigerator between 2°C - 8°C for no longer than 24 hours.

## **How many injections will you need**

Your doctor will decide how long you should continue to be treated with DBL Desferrioxamine Mesylate for Injection BP.

## **If you are given too much DBL Desferrioxamine Mesylate for Injection BP**

As DBL Desferrioxamine Mesylate for Injection BP is given to you under the supervision of a doctor, it is very unlikely that you will receive too much.

**However, if you think that you have been given too much DBL Desferrioxamine Mesylate for Injection BP and/or if you experience severe side effects, you should immediately:**

- contact your doctor or nurse if you are already in hospital, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital, especially if you are receiving ongoing treatment at home.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while I am being treated with DBL Desferrioxamine Mesylate for Injection BP?**

### **Things you should do**

Remind any doctor, nurse, pharmacist or dentist you visit that you are being treated with DBL Desferrioxamine Mesylate for Injection BP.

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

If you become pregnant while being treated with DBL Desferrioxamine Mesylate for Injection BP, tell your doctor or pharmacist immediately.

If you are being treated with DBL Desferrioxamine Mesylate for Injection BP for a prolonged period, you should have tests to assess the amount of iron in your urine every few weeks, as advised by your doctor. Sight and hearing tests should also be repeated at three-month intervals.

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

## **Call your doctor straight away if you:**

- experience visual or hearing disturbances, seizures, breathing difficulties, flushing of the skin, hives or itchy rash or feel dizzy or lightheaded.
- have symptoms of an infection where you start to feel feverish with a sore throat or stomach pains, or general discomfort or develop shortness of breath; or experience chills, fever, have pain in your back, side or groin area, feel nauseous or vomit, and have cloudy, dark, bloody or bad smelling urine, or frequent painful urination.

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 being treated with DBL Desferrioxamine Mesylate for Injection BP until any infections clear up.

## **Things you should not do**

Do not stop taking this medicine or change the dosage without consulting with your doctor.

## **Driving or using machines**

**Avoid driving or using any machines or tools until you know how DBL Desferrioxamine Mesylate for Injection BP affects you.**

DBL Desferrioxamine Mesylate for Injection BP may cause dizziness, light-headedness and sight or hearing disturbances in some people.

Make sure you know how you react to this medicine and do not drive a car, operate machinery, or do anything else that could be dangerous.

## **Drinking alcohol**

No information available.

## **Looking after your medicine**

DBL Desferrioxamine Mesylate for Injection BP will usually be stored in the pharmacy or on the ward.

If you are going to be treated at home, store DBL Desferrioxamine Mesylate for Injection BP below 25°C. It is important to keep it in the carton until use, as it must be protected from light.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Do not use this medicine after the expiry date, or if the packaging is torn or shows signs of tampering.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to be given this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>● pain, swelling or blisters at the injection site</li><li>● headache</li><li>● urine (wee) changes to orange-rose colour</li><li>● black stools/poo</li><li>● loss of feeling in hands, feet, arms or legs, numbness or tingling (pins and needles).</li><li>● aching joints and/or muscles</li></ul>	<b>Speak to your doctor or nurse if you have any of these side effects and they worry you.</b>

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● fatigue.</li> </ul>	
<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● blurred vision or other problems with sight</li> <li>● hearing problems</li> <li>● skin rash, itchiness</li> <li>● redness or flushing of the skin</li> <li>● nausea, vomiting or diarrhoea</li> <li>● abdominal or stomach cramps</li> <li>● problems with urination (weeing) or dark, cloudy, bloody or bad smelling urine/wee</li> <li>● bone pain, leg cramps or involuntary muscle contractions</li> <li>● headache</li> <li>● signs of frequent infection, such as fever, chills, sore throat or mouth ulcers</li> <li>● unexplained or easy bruising, nosebleeds and bleeding gums,</li> </ul>	<p><b>Tell your doctor or nurse straight away, or go to the Emergency Department at your nearest hospital if you notice any of these side effects.</b></p> <p>These may be more serious side effects. You may need urgent medical attention.</p>

<b>Side effects</b>	<b>What to do</b>
<p>prolonged bleeding from cuts</p> <ul style="list-style-type: none"> <li>● sudden swelling below or on the skin surface, or around the eyes, lips or throat.</li> <li>● light-headedness or dizziness</li> <li>● seizures/fits</li> <li>● irregular heartbeat, chest pain</li> <li>● unusually cold hands and feet</li> <li>● shortness of breath, rapid breathing</li> <li>● confusion, memory problems</li> <li>● blueish colouring of skin</li> <li>● tightness of chest with wheezing or coughing and difficulty breathing</li> <li>● Patients on dialysis may experience personality changes, headache, confusion, paralysis of part or all of the body, stiff neck, abnormal, speech and eye movements.</li> </ul>	

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.**

## **7. Product details**

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

### **What DBL Desferrioxamine Mesylate for Injection BP contains**

<b>Active ingredient (main ingredient)</b>	Desferrioxamine mesilate
<b>Other ingredients</b>	There are no other ingredients

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

**You should not be given this medicine if you are allergic to desferrioxamine mesilate.**

## **What DBL Desferrioxamine Mesylate for Injection BP looks like**

DBL Desferrioxamine Mesylate for Injection BP is a white to cream coloured powder.

DBL Desferrioxamine Mesylate for Injection BP is available in 2 strengths:

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

## **Who distributes DBL Desferrioxamine Mesylate for Injection BP**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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