



## **Iron Sucrose Injection USP 50mg/2.5ml, 100mg/5ml, 200mg, 2ml**

(Iron Sucrose Injection)

### **Package leaflet: Information for the user**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Iron Sucrose is and what it is used for
2. What you need to know before Iron Sucrose is given to you
3. How Iron Sucrose is given
4. Possible side effects
5. How to store Iron Sucrose
6. Contents of the pack and other information

## **1. What Iron Sucrose is and what it is used for**

Iron Sucrose is a medicine that contains iron.

Medicines that contain iron are used when you do not have enough iron in your body. This is called “iron deficiency”.

Iron Sucrose is given when:

- You cannot take iron by mouth - such as when iron tablets make you feel ill.
- You have taken iron by mouth - and it has not worked.

## **2. What you need to know before Iron Sucrose is given to you**

### **You must not receive Iron Sucrose if:**

- You are allergic (hypersensitive) to the product or any of the other ingredients of this medicine (listed in section 6).
- You have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.
- You have anaemia which is not caused by a shortage of iron.
- You have too much iron in your body or a problem in the way your body uses iron.

You must not be given Iron Sucrose if any of the above apply to you. If you are not sure, talk to your doctor before having Iron Sucrose.



## **Warnings and precautions**

Talk to your doctor or nurse before receiving Iron Sucrose if:

- You have a history of medicine allergy.
- You have systemic lupus erythematosus.
- You have rheumatoid arthritis.
- You have severe asthma, eczema or other allergies.
- You have any infections.
- You have liver problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you are given Iron Sucrose.

## **Other medicines and Iron Sucrose**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Iron Sucrose can affect the way some other medicines work. Also some other medicines can affect the way Iron Sucrose works.

In particular tell your doctor or pharmacist if you are taking:

- Medicines that contain iron which you take by mouth. These may not work if they are taken at the same time that Iron Sucrose is given to you.

## **Pregnancy and breast-feeding**

Iron Sucrose has not been tested in women who are in the first three months of their pregnancy. It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby.

If you become pregnant during treatment, you must ask your doctor for advice.

Your doctor will decide whether or not you should be given this medicine.

If you are breast-feeding, ask your doctor for advice before you are given Iron Sucrose.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

## **Driving and using machines**

You may feel dizzy, confused or light-headed after being given Iron Sucrose. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure.

## **3. How Iron Sucrose is given**

Your doctor will decide how much Iron Sucrose to give you. He or she will also decide how often you need it and for how long. Your doctor will do a blood test to help work out the dose.

Your doctor or nurse will administer Iron Sucrose in one of the following ways:

- Slow injection into your vein – 1 to 3 times per week.



- As an infusion (drip) into your vein – 1 to 3 times per week.
- During dialysis – it will be put into the venous line of the dialysis machine.

Iron Sucrose will be administered in a structure where immunoallergic events can receive appropriate and prompt treatment.

You will be observed for at least 30 minutes by your doctor or nurse after each administration.

Iron Sucrose is a brown liquid and so the injection or infusion will look brown.

#### **Use in children**

Iron Sucrose is not recommended for use in children.

## **4. Possible side effects**

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Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Allergic reactions** (uncommon)

If you have an allergic reaction, tell your doctor or nurse straight away. The signs may include:

- Low blood pressure (feeling dizzy, light-headed or faint).
- Swelling of your face.
- Difficulty breathing.

In some patients these allergic reactions (rare) may become severe or life-threatening (known as anaphylactoid/anaphylactic reactions).

Tell your doctor or nurse straight away if you think you are having an allergic reaction.

#### **Other side effects include:**

##### **Common** (may affect up to 1 in 10 people)

- Changes in your taste such as a metallic taste. This does not usually last very long.
- Low blood pressure or high blood pressure.
- Feeling sick (nausea).
- Reactions around the site of injection/ infusion such as pain, irritation, itching, haematoma or discolouration following the leakage of the injection into the skin.

##### **Uncommon** (may affect up to 1 in 100 people)

- Headache or feeling dizzy.
- Stomach pain or diarrhoea.
- Being sick (vomiting).
- Wheezing, difficulty in breathing.
- Itching, rash.
- Muscle spasms, cramps or pain.
- Tingling or “pins and needles”.
- Reduced sensation of touch.
- Vein inflammation.
- Flushing burning sensation.
- Constipation.



- Joint pain.
- Pain in limbs.
- Back pain.
- Chills.
- Weakness, tiredness.
- Swelling of hands and feet.
- Pain.
- Increased levels of liver enzymes (ALT, AST, GGT) in the blood.
- Increased serum ferritin levels.

**Rare** (may affect up to 1 in 1,000 people)

- Fainting.
- Sleepiness or drowsiness.
- Pounding heart beat (palpitations).
- Changes to the colour of your urine.
- Chest pain.
- Increased sweating.
- Fever.
- Increased lactate dehydrogenase in the blood.

Other side effects with unknown frequency include: feeling less alert, feeling confused; loss of consciousness; anxiety; trembling or shaking; swelling of your face, mouth, tongue or throat which may cause difficulty in breathing; low pulse rate; fast pulse rate; circulatory collapse; vein inflammation causing the formation of a blood clot; acute narrowing of the airways; itching, hives, rash or skin redness; cold sweat; general feeling of illness; pale skin; sudden life-threatening allergic reactions.

Flu-like illness may occur a few hours to several days after injection and is typically characterised by symptoms such as high temperature, and aches and pains in muscles and joints.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

## **5. How to store Iron Sucrose**

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Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP.

Do not store above 25°C. Do not freeze. Keep the ampoules or vials in the outer carton.

Once the Iron Sucrose ampoules or Iron Sucrose vials have been opened, they should be used immediately. After dilution with sodium chloride solution, the diluted solution should be used immediately. Iron Sucrose will normally be stored for you by your doctor or the hospital.

## **6. Contents of the pack and other information**

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### **What Iron Sucrose contains**

The active substance is iron (as iron sucrose).

a) Iron Sucrose Injection USP 50mg/2.5ml  
Each ml contains:



Iron Sucrose                    20mg/ml  
Water for Injection            q.s

b) Iron Sucrose Injection USP 100mg/5ml

Each ml contains:

Iron Sucrose                    20mg/ml  
Water for Injection            q.s

c) Iron Sucrose Injection USP 200mg/10ml

Each ml contains:

Iron Sucrose                    20mg/ml  
Water for Injection            q.s

The other ingredients are water for injections and sodium hydroxide.

#### **What Iron Sucrose looks like and contents of the pack**

Iron Sucrose is a dark brown, non transparent, aqueous solution.

Iron Sucrose comes in following pack-sizes:

- 5 Glass ampoules of 5 ml. Each ampoule of 5 ml corresponds to 100 mg of iron.
- 5 Glass vials of 2.5 ml. Each vial of 2.5 ml corresponds to 50 mg of iron.
- 5 Glass vials of 5 ml. Each vial of 5 ml corresponds to 100 mg of iron.

Not all pack-sizes may be marketed.

#### **7.Manufactured in India by:**

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