
Instruction for use, packing leaflets, inserts.

Package Leaflet: Information for the User

FEROBSV

Iron Sucrose Injection USP (100 mg/5 mL)

For Intravenous Use Only

Single use Ampoule

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help us by reporting any side effects you may experience.

Read this entire leaflet carefully before using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your physician.
- Iron Sucrose Injection USP 100 mg/5 mL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

FEROBSV

Iron Sucrose Injection USP 100 mg/5 mL

Each 5mL contains 100 mg Iron in the form of Ferric Hydroxide in Complex with Sucrose

1. What Iron Sucrose Injection USP 100mg/5mL Contains

The active substance of Iron Sucrose Injection USP 100 mg/5 mL is Iron (as Iron Sucrose Complex). Each 5 millilitre Ampoules contains 100 mg elemental Iron. The other ingredient is Water for Injection. Contains no preservatives. Each 5 mL ampoule contains 1.5g of sugar.

2. What Iron Sucrose Injection USP 100mg/5mL is used for

Iron Sucrose Injection USP 100 mg/5 mL is used for the treatment of patients with Iron deficiency, when oral iron preparations are ineffective or cannot be used.

Before administration, your physician will perform a blood test to calculate the dose of Iron Sucrose Injection USP 100 mg/5 mL as per your requirement.

3. Before You Receive Iron Sucrose Injection USP 100 mg/5 mL

You must not receive Iron Sucrose Injection USP 100 mg/5 mL:

- If you are allergic (hypersensitive) to Iron Sucrose or any of the other ingredients of Iron Sucrose Injection USP 100 mg/5 mL
- If you have anemia which is not caused by a shortage of iron.
- If you have too much iron in your body or a problem in the way your body uses iron.
- If you ever had asthma, eczema or other allergies
- If you have any infections
- If you have liver problems
- If you are a child. This is because it has not been studied/ documented that Iron Sucrose Injection 100 mg/5 mL is safe in children.
- If you are breastfeeding your baby. This is because it has not been shown that Iron Sucrose Injection 100 mg/5 mL is safe for breastfeeding child.
- If you are in the first three months of pregnancy.

You must not be given Iron Sucrose Injection 100 mg/5 mL if any of the above applies to you. If you are not sure, talk to your physician before receiving Iron Sucrose Injection 100 mg/5 mL. Take special care while receiving Iron Sucrose Injection 100 mg/5 mL.

Children

The use of Iron Sucrose Injection has not been adequately studied/ documented in children and therefore, Iron Sucrose Injection USP 100 mg/5 mL is not recommended for use in children.

Pregnancy and Breastfeeding:

Iron Sucrose Injection USP 100 mg/5 mL must not be given during the first three months of pregnancy. Your physician will decide if Iron Sucrose Injection USP 100 mg/5 mL can be used during the fourth to ninth month of pregnancy.

Iron Sucrose Injection USP 100 mg/5 mL is not recommended for use in breastfeeding women.

If you are pregnant or breastfeeding your baby while taking Iron Sucrose Injection USP 100 mg/5 mL, please consult your physician, pharmacist or other health care professional for advice.

Driving and using machinery

You may feel dizzy, confused or light-headed after being given Iron Sucrose Injection USP 100 mg/5 mL. If this happens, do not drive or use any tool or machines. Consult your physician if you are not sure.

Taking other medicines with Iron Sucrose Injection USP 100 mg/5 mL

Iron Sucrose Injection USP 100 mg/5 mL should not be given together with oral iron preparations.

If you are taking other medicines on regular basis including complementary or traditional medicines, the use of Iron Sucrose Injection USP 100 mg/5 mL with these medicines may cause undesirable interactions. Please consult your physician, pharmacist or other health care professional for advice.

4. How Iron Sucrose Injection USP 100 mg/5 mL Is Given

Iron Sucrose Injection USP 100 mg/5 mL will be given by a physician or other healthcare professional.

Your physician will decide how much Iron Sucrose Injection USP 100 mg/5 mL to give you. He or she will also decide how often you need it and for how long. Your physician will do a blood test to help work out the dose.

If you never had Iron Sucrose Injection USP 100 mg/5 mL before, you will have a small test dose. This is to check that you are not allergic to it.

How Iron Sucrose Injection USP 100 mg/5 mL is given

Iron Sucrose Injection USP 100 mg/5 mL can be given in 3 different 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 limb of the dialyser.

You must not receive more than 2 ampoules of Iron Sucrose Injection USP 100 mg/5 mL per treatment. Iron Sucrose Injection USP 100 mg/5 mL is a brown liquid so the injection or infusion will look brown.

Children

Iron Sucrose Injection USP 100 mg/5 mL is not recommended for use in children.

If you are given more Iron Sucrose Injection USP 100 mg/5 mL than you should have

In the event of over dosage, consult your physician or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

5. POSSIBLE SIDE EFFECTS

Like all medicines, Iron Sucrose Injection USP 100 mg/5 mL can cause side effects, although not everybody experiences them.

Allergic reactions (affects less than 1 in 1,000 people)

If you have an allergic reaction, tell your physician or nurse straight away.

The signs of allergic reactions may include:

Low blood pressure (feeling dizzy, light-headed or faint).

Swelling of your face.

Difficulty breathing.

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

Other side effects include:

Frequent (affects less than 1 in 10 people)

Changes in your taste such as a metallic taste. This does not usually last very long.

Less Frequent (affects less than 1 in 100 people)

- Fast pulse rate.
- Headache or feeling dizzy.
- Low blood pressure and collapse.
- Pounding heart beat (palpitations).
- Stomach pain or diarrhoea.
- Feeling sick (nausea) or being sick (vomiting).
- Wheezing, difficulty in breathing.

- Itching, hives, rash or skin redness.
- Muscle cramps or muscle pain.
- Tingling or “pins and needles”.
- Flushing.
- Fever or shivering.
- Chest pain and chest tightness.
- Reactions around the site of injection such as inflammation, a feeling of burning and swelling.

Rare (affects less than 1 in 1,000 people)

- Fainting.
- Loss of consciousness.
- A feeling of burning.
- Swelling (dropsy).
- Pain in joints.
- Swelling of hands and feet (fluid retention).
- Tiredness, weakness or general feeling of illness.

Other side effects include

Feeling less alert, light-headed or confused; swelling of your joints, face and tongue; increased sweating; back pain; low pulse rate; changes in the colour of urine.

Reporting of side effects

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please consult your physician or health care professional.

Not all side effects reported for Iron Sucrose Injection USP 100 mg/5 mL are included in this leaflet. Should your general health worsen while taking Iron Sucrose Injection USP 100 mg/5 mL, please consult your physician, pharmacist or other health care professional for advice.

6. Storing and Disposing of Iron Sucrose Injection USP 100 mg/5 mL

Store below 30⁰ C. Do not freeze; Keep out of reach from children

Keep the ampoules in the Original Pack.

Do not use Iron Sucrose Injection USP after the expiry date which is mentioned on the carton.

Once the Iron Sucrose Injection USP 100 mg/5 mL ampoule have been opened, it should be used immediately. After dilution with Sodium Chloride solution, the diluted solution should be used immediately.

Iron Sucrose Injection USP 100 mg/5 mL will normally be stored for you by your physician or the hospital pharmacy.

Iron sucrose injection USP 100 mg/5 mL is intended for single use only. After first opening of the ampoule /container, the remaining or unused Iron sucrose injection USP 100 mg/5 mL should be discarded.

7. PRESENTATION

5 mL brown coloured solution filled in ampoule. Printed Carton Box of 5 Such Ampoules in a Plastic tray along with a Prescribing Information and Patient Information Leaflet.

8. IDENTIFICATION

A homogeneous brown liquid, free from particulate matter filled with 5 mL in flint ampoule with purple color snap off, USP Type-I.

9. Registration Number

10. Name and Address of the Manufacturer

Global Pharmatech Pvt. Ltd

No.32, Phase-I,

Sipcot Industrial Complex,

Hosur-635 126,

Tamil Nadu, INDIA.