

## PATIENT COUNSELLING INFORMATION

### Rx Iron Sucrose Injection USP 100 mg

**Imax-s<sup>TM</sup>** I.V. USE ONLY

#### **Read the entire leaflet carefully before you start taking this medicine:**

- 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.
- 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.

#### **1. What is Imax-s<sup>TM</sup> and what is it used for?**

Imax-s<sup>TM</sup> 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”.

Imax-s<sup>TM</sup> 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 you take Imax-s<sup>TM</sup>?**

*You must not receive Imax-s<sup>TM</sup> if:*

- You are allergic (hypersensitive) to the product or any of the other ingredients of this medicine
- 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 Imax-s<sup>TM</sup> if any of the above apply to you. If you are not sure, talk to your doctor before having Imax-s<sup>TM</sup>.

#### ***Warnings and precautions***

*Talk to your doctor before receiving Imax-s<sup>TM</sup> 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 Imax-s<sup>TM</sup>.

### ***Pregnancy, breast-feeding and fertility***

Imax-s™ 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 Imax-s™.

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 Imax-s™. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure.

### **Other medicines and Imax-s™:**

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 Imax-s™ can affect the way some other medicines work. Also some other medicines can affect the way Imax-s™ 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 Imax-s™ is given to you.

## **3. How Imax-s™ is given?**

Your doctor will decide how much Imax-s™ 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 Imax-s™ 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. Imax-s™ 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. Imax-s™ is a brown liquid and so the injection or infusion will look brown.

### **Use in children**

Imax-s™ is not recommended for use in children.

## **4. What are the possible side effects of Imax-s™?**

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.
- Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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.
- Abnormal sensation, typically tingling or pricking.
- Partial or total loss of sensation in part of body
- Shortness of breath
- 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.

#### 5. How to store Imax-s<sup>TM</sup>?

**Store at controlled room temperature. Do not freeze. Protect from light.**

Keep out of reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

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*For further information please write to:*



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