

PATIENT INFORMATION LEAFLET

Encifer Injection

Iron Sucrose Injection USP

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

a) WHAT ENCIFER IS AND WHAT IT IS USED FOR

b) BEFORE YOU USE ENCIFER

c) HOW TO USE ENCIFER

d) POSSIBLE SIDE EFFECTS

e) HOW TO STORE ENCIFER

f) FURTHER INFORMATION

a) WHAT ENCIFER IS AND WHAT IT IS USED FOR

Encifer 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”.

Encifer 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.

b) BEFORE YOU USE ENCIFER

Do not use Encifer 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 Encifer if any of the above apply to you. If you are not sure, talk to your doctor before having Encifer.

Take special care with Encifer

Talk to your doctor or nurse before receiving Encifer 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 Encifer.

Using other medicines

Please tell your doctor, healthcare provider or pharmacist if you are taking, have recently taken any other medicines, including medicines obtained without a prescription.

This is because Encifer can affect the way some other medicines work. Also some other medicines can affect the way Encifer 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 Encifer is given to you.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or 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 Encifer.

Driving and using machines

Do not drive because 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.

c) HOW TO USE ENCIFER

Your doctor will decide how much Encifer 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 Encifer 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.

Encifer 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.

Use in children

Encifer is not recommended for use in children.

If you stop using Encifer

If you have any further questions on the use of this product, ask your doctor, healthcare provider or pharmacist.

d) POSSIBLE SIDE EFFECTS

Like all medicines, Encifer 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)

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

e) HOW TO STORE ENCIFER

Keep out of the reach and sight of children.

Do not use Encifer after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Store in a dark place 30 C. Do not freeze.

f) FURTHER INFORMATION

What Encifer contains

- The excipients are:

Sodium Hydroxide

Water for Injection

What Encifer looks like and contents of the pack

5 ampules in one Alu/PVC blister pack. One such blister packed in carton

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Marketing Authorization Holder

Emcure Pharmaceuticals Limited

Plot No. P-1 & P-2, IT-BT Park, Phase-II, M.I.D.C.,

Hinjawadi, Pune-411057, Maharashtra, India.

Manufacturing site:

Emcure Pharmaceuticals Ltd.

Plot No. J-174, J-168 & J-168/1,

MIDC, Tarapur, Boisar, Dist

Thane-401506, Maharashtra, India

3. DOCUMENT REVISION HISTORY

23.02.2024