PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

Fortihem™ 20 mg/mL (solution for injection/concentrate for solution for infusion)

Iron(III)-hydroxide sucrose complex

Contains sugar.

Read all of this leaflet carefully before you start taking FORTIHEM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.

What is in this leaflet

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

1. What FORTIHEM is and what it is used for

FORTIHEM 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”.

FORTIHEM 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 FORTIHEM is given to you

You must not receive FORTIHEM if:

- You are allergic (hypersensitive) to the product or any of the other ingredients of this medicine (listed in section 6).
- You have too much iron in your body or a problem in the way your body uses iron.
- You have anaemia which is not caused by a shortage of iron.
- You have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.
- You have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.
- If you have any liver damage of liver disorders.
- If you have acute of chronic infection.
- If you have ever had asthma, eczema, or any other allergic or anaphylactic reactions.
- If you are a child.
- If you are breastfeeding your baby.
- If you are pregnant and within your first semester.

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

Warnings and precautions:

Talk to your doctor or nurse before receiving FORTIHEM 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 FORTIHEM.

Other medicines and FORTIHEM:

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 complementary (e.g., herbal) and traditional medicines.

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

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding or are planning to have a baby, please consult your doctor, pharmacist or health care provider before taking this medicine.

FORTIHEM should not be administered to you during the first three months of your pregnancy. Your doctor will decide if FORTIHEM can be used during the fourth to ninth months of your pregnancy.

The safety of FORTIHEM in breastfeeding has not been established. If you are breastfeeding, ask your doctor for advice before you are given FORTIHEM.

Driving and using machines:

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

3. How FORTIHEM is given

Your doctor will decide how much FORTIHEM 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 FORTIHEM in one of the following ways:

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

FORTIHEM 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.

Your doctor will tell you how long your treatment with FORTIHEM will last. Do not stop treatment early. If you have the impression that the effect of FORTIHEM is too strong or too weak, tell your doctor or pharmacist.

Since a health care provider will administer FORTIHEM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Use in children:

FORTIHEM is not recommended for use in children.

4. Possible side effects

FORTIHEM can cause side effects.

Not all side effects reported for FORTIHEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FORTIHEM, please consult your health care provider for advice.

If any of the following happen, stop taking FORTIHEM and tell your doctor immediately or go to the nearest casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FORTIHEM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the nearest casualty department at your nearest hospital if you notice any of the following:

- Chest pain.
- Angina.
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Difficulty breathing.
- Signs of recurrent infections such as fever or sore throat.
- Less urine than is normal for you.
- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- If you experience a complete lack of taste.

- Low blood pressure or high blood pressure.
- Feeling sick (nausea).
- If you get infections or experience redness at the injection sites.

Less frequent side effects:

- 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.
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side affects you can help provide more information on the safety of FORTIHEM.

Side-effects can also be reported directly to the Holder of the Certificate of Registration at pvi1j.solutions.iqvia.com or to adverse.event.sac@sandoz.com.

5. How to store FORTIHEM

Store all medicines out of reach of children.

Store at or below above 25 °C.

Do not freeze.

Store in the original package.

Use immediately after opening.

FORTIHEM will normally be stored for you by your doctor or health care provider.

6. Contents of the pack and other information

What FORTIHEM contains:

Each ampoule contains 100 mg iron as iron(III)-hydroxide sucrose complex per 5 mL solution; 20 mg iron per 1 mL.

The other ingredients are water for injection and sodium hydroxide 5N (pH adjuster).

What FORTIHEM looks like and contents of the pack:

FORTIHEM is a dark brown, colloidal, aqueous solution.

Immediate container:

FORTIHEM, solution for injection/concentrate for solution for infusion is filled in clear hydrolytic glass (Ph. Eur., Type I) ampoules.

Each ampoule contains 5 mL of solution, according to the proposed packaging size of the medicine.

Secondary container:

A carton box containing a specific plastic holding case, which there in after holds 5 ampoules along with the patient information leaflet.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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