1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S3

FERINJECT® 50 mg/ml solution for injection/infusion

Ferric carboxymaltose

Sugar free

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share FERINJECT® with any other person.
- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What FERINJECT® is and what it is used for

FERINJECT® 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.

FERINJECT® is used to treat iron deficiency when:

- oral iron is not effective enough.
- you cannot tolerate oral iron.
- your doctor decides you need iron very quickly to build up your iron stores.

The doctor will determine whether you have iron deficiency by performing a blood test.

2. What you need to know before FERINJECT® is administered to you

Do not receive FERINJECT®:

- If you are allergic (hypersensitive) (allergic) to ferric carboxymaltose or any of the other ingredients of FERINJECT® (listed in section 6).
- If you have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.

- If you have anaemia not caused by iron deficiency.
- If you have iron overload (too much iron in your body) or disturbances in utilisation of iron.

Warnings and precautions

Talk to your doctor before receiving FERINJECT® or during treatment if you have:

- A history of medicine allergy.
- Systemic lupus erythematosus.
- Rheumatoid arthritis.
- Severe asthma, eczema or other allergies.
- An infection.
- Liver disorders.
- Or have had low levels of phosphate in the blood.

Incorrect administration of FERINJECT® may cause leakage of the product at the administration site, which may lead to irritation of the skin and potentially long lasting brown discolouration at the site of administration. The administration must be stopped immediately when this occurs.

Children and adolescents

FERINJECT® should not be given to children under 18 years.

Other medicines and FERINJECT®

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

FERINJECT® should not be given together with oral iron preparations, as the absorption of oral preparations is impaired.

Pregnancy, breastfeeding and fertility

Pregnancy

There is limited data from the use of FERINJECT® in pregnant women. 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 FERINJECT®.

Breastfeeding

If you are breastfeeding, ask your doctor for advice before you are given FERINJECT®. It is unlikely that FERINJECT® represents a risk to the nursing child.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before FERINJECT® is administered to you.

Driving and using machines

It is not always possible to predict to what extent FERINJECT® may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which FERINJECT® affects you (see section 4).

After receiving FERINJECT®, you may feel dizzy, confused or lightheaded. FERINJECT® may impair the ability to drive or operate machines.

FERINJECT® contains sodium

FERINJECT® contains up to 0,24 mmol (or 5,5 mg) sodium per millilitre of undiluted solution and is to be taken into consideration by patients on a controlled sodium diet.

3. How FERINJECT® will be administered to you

You will not be expected to give yourself FERINJECT®. It will be given to you by a person who is qualified to do so.

Your doctor will decide how much to give you, how often you need it and for how long. Your doctor will perform a blood test to determine the dose you need. Your doctor or nurse will administer FERINJECT® undiluted by injection, during dialysis, or diluted by infusion:

- By injection, you may receive up to 20 mL of FERINJECT®, corresponding to 1 000 mg of iron, once a week directly into the vein.
- If you are on dialysis, you may receive FERINJECT®. during a haemodialysis session via the dialyser.
- By infusion, you may receive up to 20 mL of FERINJECT®, corresponding to 1 000 mg of iron, once a week directly into the vein. Because FERINJECT® is diluted with sodium chloride solution for the infusion, it may have a volume of up to 250 mL and appear as a brown solution.

FERINJECT® 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.

If you receive more FERINJECT® than you should

Since a healthcare professional will administer FERINJECT®, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
Overdose can cause accumulation of iron in storage sites. Your doctor will monitor iron parameters such as serum ferritin and transferrin to avoid iron accumulation.

4. Possible side effects

FERINJECT® can cause side effects
Not all side effects reported for FERINJECT® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while FERINJECT® is administered to you, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, FERINJECT® administration should be stopped and your doctor will decide if you should immediately go to the 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,
- chest pain which can be a sign of Kounis syndrome (a serious allergic reaction).

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

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

- Worsening of tiredness, muscle or bone pain (pain in your arms or legs, joints or back). That may be a sign of a decrease in blood phosphorous which might cause your bones to become soft (osteomalacia). Your doctor may also check the levels of phosphate in your blood, especially if you need a number of treatments over time.
- Fast or irregular heartbeat.

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:

- Headache, dizziness;
- flushing, increased in blood pressure (hypertension);
- nausea;
- injection site reactions.

Less frequent side effects:

- A feeling of numbness or burning ("pins-and-needles") in hands, arms, legs or feet (paraesthesia);
- taste disturbances (dysgeusia);
- lowered blood pressure (hypotension);
- vomiting, indigestion, abdominal pain, constipation, diarrhoea;
- fever, a sudden feeling of cold with shivering (rigors);
- an increase in certain liver enzymes called aspartate aminotransferase, gamma-glutamyltransferase and alanine aminotransferase;
- an increase in an enzyme called lactate dehydrogenase.

Ask your doctor for more information to interpret the laboratory results.

Side effects with unknown frequency:

- Excessive wind (flatulence);
- anxiety;
- inflammation in a vein, symptoms include redness, warmth and pain in the affected area (phlebitis);
- general feeling of unwellness (malaise);
- flu-type symptoms;
- unhealthy pale appearance (pallor);
- skin discolouration at other areas of the body than the administration site.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of FERINJECT®.

5. How to store FERINJECT®

Store at or below 30˚C

Do not freeze.

Do not use after the expiry date stated on the label.

Store in the original package.

KEEP OUT OF REACH OF CHILDREN

Once the FERINJECT® vials have been opened, they should be used immediately. After dilution with sodium chloride solution, the diluted solution should be used immediately.

FERINJECT® will normally be stored for you by your doctor or the hospital.

6. Contents of the pack and other information

What FERINJECT® contains

- The active substance:

One millilitre of solution contains 50 mg of iron as ferric carboxymaltose

One millilitre of solution contains up to 0,24 mmol (5,5 mg) sodium.

The other ingredients are:

Water for injection

What FERINJECT® looks like and contents of the pack

FERINJECT®, solution for injection/infusion is a dark brown, non-transparent solution.

FERINJECT® is supplied in glass vials of 10 ml solution, corresponding to 500 mg iron.

FERINJECT® is available as 10 ml vials.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 118 088

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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