1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FERINJECT® 50 mg iron/ml solution for injection/infusion ferric carboxymaltose.

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

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.
- Ask your doctor, pharmacist, nurse if you need more information or advice.

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

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

3. How to take FERINJECT®

4. Possible side effects

5. How to store FERINJECT®

6. Contents of the pack and other information

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 for the treatment of patients with iron deficiency, when oral iron preparations are ineffective or cannot be used. The aim of the therapy is to replenish body iron stores and to remedy anaemia, a lack of red blood cells due to iron deficiency.

Before administration, your doctor will perform a blood test to calculate the dose of **FERINJECT®** you require.

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

Do not receive FERINJECT®:

- if you are hypersensitive (allergic) to ferric carboxymaltose or any of the other ingredients of **FERINJECT®,**
- 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,
- during the first three months of pregnancy.

Warnings and precautions

Talk to your doctor before **FERINJECT®** is being administered to you or during treatment if you have:

- an infection, asthma, eczemas, allergies or liver disorders.

Children and adolescents

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

Other medicines and FERINJECT®

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of FERINJECT® with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice

Pregnancy

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given **FERINJECT®**.

Breast-feeding

It is unlikely that **FERINJECT®** represents a risk to the nursing child.

Driving and using machines

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 to take FERINJECT®

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

Test dose:

Before receiving your FERINJECT® dose, your doctor will administer a test dose consisting of a smaller volume into your vein. This is to ensure that you are not allergic to FERINJECT®.

Your doctor can administer **FERINJECT®** by three possible routes: undiluted by injection, during dialysis, or diluted by drip infusion.

- By injection, you may receive up to 4 ml of **FERINJECT®**, corresponding to 200 mg of iron, per day directly into the vein. You may receive this dose once to three times a week.
- If you are on dialysis, you may receive **FERINJECT®** during a haemodialysis session via the dialyser.
- By drip infusion, you may receive up to 20 ml of **FERINJECT®**, corresponding to 1000 mg of iron, once a week directly into the vein. Because **FERINJECT®** is diluted with sodium chloride solution for the drip infusion, it may have a volume of up to 250 ml and appear as a brown solution.

Your doctor will take responsibility for calculating the appropriate dose and choosing the route, frequency and duration of your treatment.

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 while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for

advice.

Some of these side effects are serious. Tell your doctor immediately if you experience any of these side effects listed below.

The following symptoms are frequent: headache, dizziness, nausea, abdominal pain, constipation, diarrhoea, rash, injection site reactions.

The following symptoms are less frequent: chest pain, rigors, malaise, peripheral oedema, hypersensitivity and serious allergic reactions, paraesthesia, hypotension, flushing, taste disturbance, vomiting, dyspepsia, flatulence, itchiness, hives (urticaria), muscle pain, back pain, joint pain, fever, fatigue with bone pain, ~~S~~shortness of breath (dyspnoea).

Some blood tests may change.
The following changes in blood tests are frequent: decrease in blood phosphorus and increase of a certain liver enzyme called alanine aminotransferase.

The following changes in blood tests are less frequent: increase in certain liver enzymes called aspartate aminotransferase and gamma-glutamyltransferase and increase in an enzyme called lactate dehydrogenase. Ask your doctor for more information.

If any of the side effects get serious, should your general health worsen while receiving **FERINJECT®** or if you notice any side effects not listed in this leaflet, please tell your doctor or other healthcare professional.

Reporting of side effects

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

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

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 milliliter of solution contains 50 mg of iron as ferric carboxymaltose.

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

The other ingredients are:

Water for injections

What FERINJECT® looks like and contents of the pack

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

FERINJECT® is available as 10 ml vials.

REGISTRATION NUMBER

45/8.3/0948

NAME AND ADDRESS OF REGISTRATION HOLDER

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

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