FERINJECT®

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about FERINJECT. It does not contain all the available information. This does not replace talking with your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of using FERINJECT against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your doctor.

Keep this leaflet.
You may need to read it again.

WHAT IS FERINJECT

FERINJECT is an intravenous iron preparation, a medicine that is used in the treatment of iron deficiency conditions. It contains iron in the form of ferric carboxymaltose, an iron carbohydrate compound. Iron is an essential element required for the oxygen-carrying capacity of haemoglobin in red blood cells and of myoglobin in muscle tissue. Moreover, iron plays an important role in many other vital processes in the human body.

WHAT FERINJECT IS USED FOR

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 reduced level of haemoglobin due to iron deficiency.

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

BEFORE YOU ARE GIVEN FERINJECT

When you must not be given it

- 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,
- if you are under the age of 14 years

You must tell your doctor if

- you have an infection, asthma, eczemas, allergies or liver disorders
- you are pregnant or breastfeeding

Taking other medicines

If FERINJECT is given together with oral iron preparations, then these oral preparations will be less efficient.

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

Important information about some of the ingredients of FERINJECT

This medicinal product contains 5.5 mg (or 0.24 mmol) sodium per millilitre of undiluted solution and is to be taken into consideration by patients on a controlled sodium diet.

HOW FERINJECT IS GIVEN

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

- By injection, you may receive up to 20 mL of FERINJECT, corresponding to 1000 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. The maximum dose of FERINJECT during haemodialysis is 200 mg (4 mL).
- By 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 infusion, it may have a volume of up to 250 mL and appear as a brown solution.

Your doctor will take responsibility for determining the appropriate dose and choosing the method,

frequency and duration of your treatment.

Ferinject will be administered in a setting where possible allergic reactions can receive appropriate and prompt treatment.

You will be observed for about 30 minutes by your doctor or nurse after each administration.

Overdose

Overdose can cause accumulation of iron in storage sites. Your doctor will monitor iron parameters such as serum ferritin and transferrin saturation to avoid iron accumulation.

POSSIBLE SIDE EFFECTS

Like all medicines, FERINJECT can cause side effects, although not everybody gets them.

Clinical studies experience

Reported side effects are either common (occurring in less than 1 in 10 and more than 1 in 100 patients) or uncommon (occurring in less than 1 in 100 and more than 1 in 1000 patients).

The following symptoms were common: headache, dizziness, hypertension, flushing, nausea, injection/infusion site reactions, low blood phosphate levels.

The following symptoms were uncommon: hypersensitivity, paraesthesia, increase in heart rate (tachycardia), hypotension, difficulty breathing, taste disturbance, vomiting, dyspepsia, flatulence, abdominal pain, constipation, diarrhoea, itchiness, hives (urticaria), redness (erythema), rash, muscle pain, muscle spasm, back pain, joint pain, pain in extremity, fever, fatigue, chest pain, accumulation of fluid in the periphery, pain and chills. Long-lasting brown discoloration of the skin may occur due to leakage of the drug at the injection site.

The following symptoms were rare: anaphylactoid reactions, rigors, malaise

Some blood parameters may change temporarily, which could be detected in laboratory tests.

The following change in blood parameters is common: increase of the liver enzyme alanine aminotransferase.

The following changes in blood parameters are uncommon: increase of the liver enzymes aspartate aminotransferase, gamma-glutamyltransferase, blood lactate dehydrogenase and blood alkaline phosphatase.

Post marketing experience

As part of the continuing post-marketing surveillance of FERINJECT, the following side effects have been reported in isolated cases:

Anxiety, loss of consciousness, dizziness (vertigo), fainting (syncope), wheeze (bronchospasm), swelling (angioedema), dermatitis, pallor, face swelling and influenza like illness.

There is limited experience with the use of FERINJECT in pregnancy. Adverse effects on the fetus were seen in animal studies at maternally toxic doses. If iron treatment is needed in pregnancy, oral iron should be used where possible and FERINJECT only used where the benefit outweighs the risk.

Iron treatment including FERINJECT may worsen infection.

Ask your doctor for more information.

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

STORAGE

Keep FERINJECT out of the reach and sight of children.

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

FERINJECT should be stored in the original package and should not be stored above 30° C. FERINJECT should not be refrigerated or frozen.

Once a FERINJECT vial has been opened, it should be used immediately. After dilution with sodium chloride solution, the diluted solution should be used as soon as possible, if storage is necessary hold at 2 - 8°C for not more than 12 hours.

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

Further information

This is not all the information that is available on FERINJECT. If you need more information, ask your doctor.

PRODUCT DESCRIPTION

What it looks like

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

FERINJECT is supplied in glass vials of 2 ml solution, corresponding to 100 mg iron (AUST R: 162636), and in glass vials of 10 ml solution, corresponding to 500 mg iron (AUST R: 162641).

Active ingredient

The active substance is iron (as ferric carboxymaltose, an iron carbohydrate compound). The

concentration of iron present in the product is 50 mg per milliliter.

Inactive ingredients

The other ingredients are sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), and water for injection.

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Supplied in New Zealand by:

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Managere 2022
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