FERYXA®

Ferric carboxymaltose (fer-rik car-boxy-malt-ose) – solution for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about FERYXA. 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 FERYXA 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 FERYXA

FERYXA is an intravenous iron preparation, a medicine that is given 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 FERYXA IS GIVEN FOR

FERYXA is given 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. It is also used when there is a clinical need to deliver iron rapidly.

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

BEFORE YOU ARE GIVEN FERYXA

When you must not be given FERYXA

- if you are hypersensitive (allergic) to ferric carboxymaltose or any of the other ingredients of FERYXA,
- 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.

You must tell your doctor if
- if you are under the age of 14 years.
- you have an infection, asthma, eczemas, allergies or liver disorders.
- you are pregnant or breastfeeding.
- if you have or have had low levels of phosphate in the blood.

You should be aware that:
Intravenous iron preparations can cause severe allergic reactions. These allergic reactions may include chest pain. Tell your doctor immediately if you experience it.

Taking other medicines

If FERYXA is given together with oral iron preparations, then these oral preparations will be less effective.
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 FERYXA
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 FERYXA IS GIVEN

Your doctor can administer FERYXA by three possible routes: undiluted by injection,

during haemodialysis, or diluted by infusion.

- by injection, you may receive up to 20 mL of FERYXA, corresponding to 1000 mg of iron, once a week directly into the vein.
- if you are on dialysis, you may receive FERYXA during a haemodialysis session via the dialyser. The maximum dose of FERYXA during haemodialysis is 200 mg (4 mL).
- by infusion, you may receive up to 20 mL of FERYXA, corresponding to 1000 mg of iron, once a week directly into the vein. Because FERYXA 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. You may be re-assessed after 4 weeks to determine whether you need more FERYXA injections. FERYXA 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.

In patients with liver disorders, iron status will be carefully monitored by the doctor to avoid iron overload.

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.

The risk of accidental overdosing is minimal.

POSSIBLE UNWANTED EFFECTS

Like all medicines, FERYXA can cause unwanted 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, high blood pressure, flushing, nausea, injection/infusion site reactions, low blood phosphate levels.

The following symptoms were uncommon: allergic reaction, tingling or numbness of the hands or feet, fast heart rate (tachycardia), low blood pressure, difficulty breathing, taste disturbance, vomiting, indigestion, wind, stomach pain, constipation, diarrhoea, itchiness, hives (urticaria), redness of skin (erythema), rash, muscle pain, muscle spasm, back pain, joint pain, pain in extremity, fever, fatigue, chest pain, swelling of hands, ankles or feet, 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, generally feeling unwell.

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

The following changes in blood parameters are uncommon: increase of the liver enzyme alanine aminotransferase, 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 FERYXA, the following side effects have been reported:

Anxiety, loss of consciousness, dizziness (vertigo), feeling faint (pre-syncope), fainting (syncope), wheeze (bronchospasm), swelling (angioedema), dermatitis, pallor, face swelling, influenza like illness, low blood phosphate levels which might cause your bones to become soft (hypophosphateamic osteomalacia), skin discolouration distant to the injection site and chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

There is no efficacy or safety data on the use of FERYXA in pregnancy before 16 weeks' gestation. Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron.

There is limited experience with the use of FERYXA in women

in pregnancy from 16 weeks' gestation). If iron treatment is needed in pregnancy, oral iron should be used where possible and FERYXA only used where the benefit outweighs the risk.

Slow heartbeat may occur in unborn babies whose mothers have been administered intravenous iron due to allergic reactions in the mother.

Iron treatment including FERYXA 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.

AFTER TAKING FERYXA

Storage

Keep FERYXA out of the reach and sight of children.

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

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

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

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

Product is for single use in one patient only. Discard any residue.

Further information

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

PRODUCT DESCRIPTION

What it looks like

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

FERYXA is supplied in the following presentations:

- 2 mL of solution in a glass vial containing the equivalent of 100 mg of iron,
- 10 mL of solution in a glass vial containing the equivalent of 500 mg of iron, or
- 20 mL of solution in a glass vial containing the equivalent of 1000 mg of iron.

Not all strengths may be marketed.

Ingredients

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 millilitre.

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

Supplier

Supplied in New Zealand by:
Seqirus (NZ) Ltd
PO Box 62590
Greenlane, Auckland 1546
New Zealand
Tel: 0800 502 757

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