

FERRIC CARBOXYMALTOSE SANDOZ[®]

Ferric carboxymaltose (fer-rik car-boxy-mal-tose) – solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ferric Carboxymaltose Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FERRIC CARBOXYMALTOSE SANDOZ against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT IS FERRIC CARBOXYMALTOSE SANDOZ

Ferric Carboxymaltose Sandoz 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 FERRIC CARBOXYMALTOSE SANDOZ IS GIVEN FOR

Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz you require.

BEFORE YOU ARE GIVEN FERRIC CARBOXYMALTOSE SANDOZ

When you must not be given FERRIC CARBOXYMALTOSE SANDOZ

- if you are hypersensitive (allergic) to ferric carboxymaltose or any of the other ingredients of Ferric Carboxymaltose Sandoz,

- 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 Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz

This medicinal product contains 5.9 mg (or 0.26 mmol) sodium per millilitre of undiluted solution and is

to be taken into consideration by patients on a controlled sodium diet.

HOW FERRIC CARBOXYMALTOSE SANDOZ IS GIVEN

Your doctor can administer Ferric Carboxymaltose Sandoz by three possible routes: undiluted by injection, during haemodialysis, or diluted by infusion.

- by injection, you may receive up to 20 mL of Ferric Carboxymaltose Sandoz, corresponding to 1000 mg of iron, once a week directly into the vein.
- if you are on dialysis, you may receive Ferric Carboxymaltose Sandoz during a haemodialysis session via the dialyser. The maximum dose of Ferric Carboxymaltose Sandoz during haemodialysis is 200 mg (4 mL).
- by infusion, you may receive up to 20 mL of Ferric Carboxymaltose Sandoz, corresponding to 1000 mg of iron, once a week directly into the vein. Because Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz injections. Ferric Carboxymaltose Sandoz 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, Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz, 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 (hypophosphataemic 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 Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz in women in pregnancy from 16 weeks' gestation). If iron treatment is needed in pregnancy, oral iron should be used where possible and Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz 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 FERRIC CARBOXYMALTOSE SANDOZ

Storage

Keep Ferric Carboxymaltose Sandoz out of the reach and sight of children.

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

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

Once a Ferric Carboxymaltose Sandoz 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.

Ferric Carboxymaltose Sandoz 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 Ferric Carboxymaltose Sandoz. If you need more information, ask your doctor.

PRODUCT DESCRIPTION

What it looks like

Ferric Carboxymaltose Sandoz, solution for injection/infusion is a dark brown, non-transparent solution.

Ferric Carboxymaltose Sandoz 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 Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel: 1800 726 369

Supplied in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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