FERINJECT ®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor, nurse, or pharmacist.

1. Why am I being given FERINJECT?

FERINJECT contains the active ingredient ferric carboxymaltose. FERINJECT is used to treat adults and adolescents aged 14 years and older with iron deficiency and children aged 1 to 13 years with iron deficiency anaemia, when oral iron preparations are ineffective or cannot be used.

For more information, see Section 1. Why am I using FERINJECT? in the full CMI.

2. What should I know before I am given FERINJECT?

Do not use if you have ever had an allergic reaction to ferric carboxymaltose or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use FERINJECT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FERINJECT and affect how it works. If FERINJECT is given together with oral iron preparations, then these oral preparations will be less effective.

4. How do I use FERINJECT?

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

More instructions can be found in Section 4. How do I use FERINJECT? in the full CMI.

5. What should I know while using FERINJECT?

Things you should do	• Intravenous iron preparations can cause severe allergic reactions. These allergic reactions may include chest pain. Tell your doctor immediately if you experience it. •
Things you should not do	• Do not use this medicine if you have anaemia **not** caused by iron deficiency • Do not use this medicine if you have iron overload (too much iron in your body) or disturbances in utilisation of iron • Do not give this medicine to children under 1 year.
Looking after your medicine	• FERINJECT will normally be stored for you by your doctor or the hospital

For more information, see Section 5. What should I know while using FERINJECT? in the full CMI.

6. Are there any side effects?

Common side effects include headache, dizziness, high blood pressure, flushing, nausea, and injection/infusion site reactions. Persistent bone pain and joint pain may be a sign of low blood phosphate levels. Serious but rare side effects include allergic reactions which are sometimes life threatening, such as breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating, and nausea (anaphylactic reactions).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

FERINJECT ®

Active ingredient(s): Ferric carboxymaltose (fer-rik car-boxy-malt-ose) – solution for injection

Consumer Medicine Information (CMI)

This leaflet provides important information about using FERINJECT.

You should also speak to your doctor, nurse, or pharmacist if you would like further information or if you have any concerns or questions about using FERINJECT.

Where to find information in this leaflet:

1. Why am I using FERINJECT?

FERINJECT contains the active ingredient ferric carboxymaltose. FERINJECT is an intravenous iron preparation, a medicine that is given in the treatment of iron deficiency conditions. It contains ferric carboxymaltose, a carbohydrate complex containing iron. 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.

FERINJECT is given for treatment of adults as well as adolescents aged 14 years and older with iron deficiency when oral iron preparations are ineffective or cannot be used. FERINJECT is also used in children 1 to 13 years old with iron deficiency anaemia 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 FERINJECT you require.

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.

2. What should I know before I use FERINJECT?

Warnings

Always check the ingredients to make sure you can use this medicine.

Do not use FERINJECT if:

- you are allergic to ferric carboxymaltose, or any of the ingredients listed at the end of this leaflet.
- 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.

Check with your doctor if you:

- take any medicines for any other condition.
- have an infection, asthma, eczemas, allergies or liver disorders.
- you are pregnant or breastfeeding.
- if your doctor has told you that you have, or have had low levels of phosphate in the blood.

Intravenous iron preparations can cause severe allergic reactions. These allergic reactions may include chest pain. Tell your doctor immediately if you experience it.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is no efficacy or safety data on the use of FERINJECT 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 FERINJECT in women in pregnancy from 16 weeks' gestation). If iron treatment is needed in pregnancy, oral iron should be used where possible and FERINJECT 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 FERINJECT may worsen infection.

What if I am taking other medicines?

Tell your doctor, nurse, or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

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

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.

Check with your doctor, nurse, or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FERINJECT.

3. How do I use FERINJECT?

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

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 FERINJECT injections.

How much to take

Adults and adolescents aged 14 years and older:

Your doctor can administer FERINJECT by three possible routes: undiluted by injection, during haemodialysis, 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.

Children and adolescents aged 1 to 13 years:

Your doctor can administer FERINJECT undiluted by injection or diluted by infusion.

- by injection, your child may receive up to 15 mL of FERINJECT, corresponding to 750 mg of iron, once a week directly into the vein.
- by infusion, your child may receive up to 15 mL of FERINJECT, corresponding to 750 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.

If your child is on dialysis, FERINJECT should not be administered.

FERINJECT should not be given to children under 1 year.

Your or your child may receive two doses of FERINJECT with an interval of at least 7 days directly into the vein.

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.

The risk of accidental overdosing is minimal.

4. What should I know while using FERINJECT?

Things you should do

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.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using FERINJECT.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FERINJECT affects you.

Looking after your medicine

FERINJECT will normally be stored for you by your doctor or the hospital. However, if you need to store FERINJECT,

- 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 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.

5. Are there any side effects?

All medicines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse, or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Head related • headache • dizziness • flushing • taste disturbance • pallor • anxiety **Skin related** • injection/infusion site reactions • long-lasting brown discoloration of the skin may occur due to leakage of the drug at the injection site • redness of skin (erythema) • rash • dermatitis **Blood related** • low blood phosphate levels which might cause your bones to become soft (hypophosphateamic osteomalacia) • increase of the liver enzyme alanine aminotransferase, increase of the liver enzymes aspartate aminotransferase, gamma-glutamyltransferase, blood lactate dehydrogenase and blood alkaline phosphatase **Stomach related** • nausea • vomiting • indigestion • wind • stomach pain • diarrhoea • constipation **Allergy related** • generally feeling unwell • tingling or numbness of the hands or feet • itchiness • hives (urticaria) • swelling of hands, ankles or feet **Heart related** • fast heart rate (tachycardia), • high blood pressure • low blood pressure	**Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.**
Muscle and joint related • muscle pain • muscle spasm • back pain • joint pain • pain in extremity **General** • fever • fatigue • influenza type illness • pain, chills and generally feeling unwell	

Serious side effects

Serious side effects	What to do
Chest related • chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome **Head related** • feeling faint and fainting • loss of consciousness **Allergy related** • allergic reactions which sometimes can be life threatening: breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating, and nausea (anaphylactic reactions) • wheeze	**Call your doctor or nurse straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor, nurse, or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor, nurse, or pharmacist before you decide to stop taking any of your medicines.

6. Product details

This medicine is only available with a doctor's prescription.

What FERINJECT contains

Active ingredient (main ingredient)	iron (as ferric carboxymaltose, an iron carbohydrate compound). The concentration of iron present in the product is 50 mg per milliliter.
Other ingredients (inactive ingredients)	sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), and water for injection.

Do not take this medicine if you are allergic to any of these ingredients.

What FERINJECT looks like

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

FERINJECT is supplied in the following presentations:

- 2 mL of solution in a glass vial containing the equivalent of 100 mg of iron (AUST R: 162636),
- 10 mL of solution in a glass vial containing the equivalent of 500 mg of iron (AUST R: 162641), or
- 20 mL of solution in a glass vial containing the equivalent of 1000 mg of iron (AUST R: 289045).

Not all strengths may be marketed.

Who distributes FERINJECT

Distributed in Australia by:

CSL Seqirus
655 Elizabeth Street,
Melbourne, VIC 3000
Australia

1800 642 865 (Within Australia)

Sponsor
Seqirus Pty Ltd
63 Poplar Rd,
Parkville VIC 3052
Australia

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