FERRIVE®

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 given FERRIVE?

FERRIVE contains the active ingredient ferric carboxymaltose. FERRIVE 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 given FERRIVE? in the full CMI.

2. What should I know before FERRIVE is given?

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 FERRIVE is given? in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is FERRIVE given?

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

More instructions can be found in Section 4. How is FERRIVE given? in the full CMI.

5. What should I know after FERRIVE is given?

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

For more information, see Section 5. What should I know after FERRIVE is given? 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.

FERRIVE®

Active ingredient(s): *ferric carboxymaltose*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FERRIVE. **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 FERRIVE.**

Where to find information in this leaflet:

1. Why am I given FERRIVE?

FERRIVE contains the active ingredient ferric carboxymaltose. FERRIVE 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.

FERRIVE 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. FERRIVE 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 FERRIVE you require.

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

2. What should I know before FERRIVE is given?

Warnings

Do not use FERRIVE if:

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

  Always check the ingredients to make sure you can use this medicine.
- you have anaemia **not** caused by iron deficiency.
- 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.
- are pregnant or breastfeeding.
- have been told by your doctor 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 FERRIVE 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 FERRIVE in women in pregnancy from 16 weeks' gestation. If iron treatment is needed in pregnancy, oral iron should be used where possible and FERRIVE 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 FERRIVE may worsen infection.

3. 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 FERRIVE is given together with oral iron preparations, then these oral preparations will be less effective.

Important information about some of the ingredients of FERRIVE:

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 FERRIVE.

4. How is FERRIVE given?

FERRIVE 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 FERRIVE injections.

How much is given

Adults and adolescents aged 14 years and older:

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

- by injection, you may receive up to 20 mL of FERRIVE, corresponding to 1000 mg of iron, once a week directly into the vein.
- if you are on dialysis, you may receive FERRIVE during a haemodialysis session via the dialyser. The maximum dose of FERRIVE during haemodialysis is 200 mg (4 mL).
- by infusion, you may receive up to 20 mL of FERRIVE, corresponding to 1000 mg of iron, once a week directly into the vein. Because FERRIVE 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 FERRIVE undiluted by injection or diluted by infusion.

- by injection, your child may receive up to 15 mL of FERRIVE, corresponding to 750 mg of iron, once a week directly into the vein.
- by infusion, your child may receive up to 15 mL of FERRIVE, corresponding to 750 mg of iron, once a week directly into the vein. Because FERRIVE 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, FERRIVE should not be administered.

FERRIVE should not be given to children under 1 year.

You or your child may receive two doses of FERRIVE 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.

5. What should I know after FERRIVE is given?

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 FERRIVE.

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 FERRIVE affects you.

Looking after your medicine

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

- FERRIVE should be stored below 30°C in the original package.
- Once a FERRIVE 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.

6. Are there any side effects?

All medicines can have side effects. If you or your child experiences 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Skin related • injection/infusion site reactions • long-lasting brown discolouration of the skin may	**Speak to your doctor or nurse if you have any of these less serious side**

Less serious side effects	What to do
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 (hypophosphataemic 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 **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	**effects and they worry you.**

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.

7. Product details

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

What FERRIVE contains

Active ingredient (main ingredient)	iron (as ferric carboxymaltose)
Other ingredients (inactive ingredients)	sodium hydroxide (for pH adjustment) hydrochloric acid (for pH adjustment) water for injections

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

What FERRIVE looks like

FERRIVE is a dark brown, opaque, aqueous solution.

FERRIVE is supplied in the following presentation:

- 1 x 2 mL or 5 x 2 mL of solution in a glass vial containing the equivalent of 100 mg of iron (AUST R 456412),
- 1 x 10 mL or 5 x 10 mL of solution in a glass vial containing the equivalent of 500 mg of iron (AUST R 456414)
- 1 x 20 mL of solution in a glass vial containing the equivalent of 1000 mg of iron (AUST R 456413).

Who distributes FERRIVE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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FERRIVE® is a Viatris company trade mark

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