MONOFER®

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 or pharmacist.

1. Why am I using MONOFER?

MONOFER contains the active ingredient ferric derisomaltose. MONOFER is used to treat adults with iron deficiency when oral iron preparations are ineffective or cannot be used, or when there is a need to deliver iron rapidly.

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

2. What should I know before I use MONOFER?

Do not use if you have ever had an allergic reaction to MONOFER 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 MONOFER? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MONOFER and affect how it works.

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

4. How do I use MONOFER?

- Your doctor will use a blood test to determine your iron levels and calculate the dose of MONOFER you need.
- You will usually be given MONOFER in a clinical setting either by a slow injection directly from the syringe into the vein, by infusion over a longer period, or during a haemodialysis session (if you are receiving dialysis treatment).

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

5. What should I know while using MONOFER?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are being treated with MONOFER. • Tell your doctor straight away if you do not feel well while being treated with MONOFER. • Tell your doctor or visit the Emergency Department immediately if you experience signs of a severe allergic reaction.
Things you should not do	• Do not continue treatment with MONOFER if there is leakage around the injection site. If a leak occurs the treatment must be stopped by your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how MONOFER affects you.
Looking after your medicine	• MONOFER should be stored below 30°C.

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

6. Are there any side effects?

Common side effects include nausea, rash and reactions at the site of injection/infusion. Seek medical attention immediately if you experience any of the following: seizure, loss of consciousness or a severe allergic reaction. Signs of a serious allergic reaction involve: persistent low blood pressure; swelling of the tongue/airway, difficulty swallowing; symptoms involving multiple parts of the body, such as heart (drop in blood pressure, chest pains), skin (itching, hives or swelling such as the face, lips or other parts of the body), breathing (shortness of breath, wheezing, troubled breathing) or stomach (vomiting or pain in and around the stomach).

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.

MONOFER®

Active ingredient: *ferric derisomaltose*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MONOFER. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MONOFER.**

Where to find information in this leaflet:

1. Why am I using MONOFER?
2. What should I know before I use MONOFER?
3. What if I am taking other medicines?
4. How do I use MONOFER?
5. What should I know while using MONOFER?
6. Are there any side effects?
7. Product details

1. Why am I using MONOFER?

MONOFER contains the active ingredient ferric derisomaltose.

MONOFER is used to treat iron deficiency in adults when oral iron preparations are ineffective or cannot be used, or when there is a need to deliver iron rapidly.

The medicine contains iron in the form of ferric derisomaltose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another purpose.

2. What should I know before I use MONOFER?

Warnings

Do not use MONOFER if:

- you are allergic to ferric derisomaltose, 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 that is not caused by iron deficiency.
- you have too much iron (overload) or a problem with the way your body uses iron.

There is not enough information to recommend the use of MONOFER in children.

Check with your doctor if you:

- have any other medical conditions: liver problems; systemic lupus erythematosus (SLE) or a related disease; rheumatoid arthritis or other immune or inflammatory conditions; severe asthma, eczema or other allergies; ongoing bacterial infection in your blood; or acute or chronic infection.
- take any medicines for any other condition.
- are allergic to any other medicines, foods, dyes or preservatives.
- are prone to allergies.
- are older than 65 years of age.

If you are not sure whether any of the above conditions apply to you, ask your doctor. Your doctor may want to take special precautions if you have any of these conditions.

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, intend to become pregnant, or become pregnant during treatment. Your doctor will evaluate the risks and benefits of treatment with MONOFER during pregnancy.

Intravenous iron preparations may slow the heart rate of your unborn baby for a short time if you have a reaction to the medicine. Therefore, your doctor may monitor your unborn baby while you are being given your medicine.

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

It is unlikely that MONOFER represents a risk to your baby.

3. What if I am taking other medicines?

Tell your doctor 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.

MONOFER given together with oral iron preparations can reduce the absorption of oral iron.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are receiving MONOFER.

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

4. How do I use MONOFER?

How much to use

- your doctor will perform a blood test to determine the iron levels in your body.
- this will then help your doctor calculate the dose of MONOFER you require.

When to use MONOFER

How it is given:

- MONOFER should be given by your doctor or nurse in a setting where possible allergic reactions can be appropriately and promptly treated.
- the solution in the vial may be diluted with 0.9% sodium chloride, but never to concentrations less than 1 mg iron/mL and never diluted in more than 500 mL.
- MONOFER can be given by slow injection directly from the syringe into a vein, up to three times a week.
- MONOFER can also be given by infusion over a longer period. The dose may be split into weekly infusions.
- MONOFER can be given during a haemodialysis session if you are receiving dialysis treatment.
- your doctor or nurse will observe you for at least 30 minutes after your MONOFER administration.

How long your treatment will last:

- your doctor will determine how long you will need to receive treatment with MONOFER.
- you may receive a single MONOFER administration, or several administrations over several weeks.

If you use too much MONOFER

Overdose may lead to 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.

If you think that you have used too much MONOFER, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MONOFER?

Things you should do

Before having any surgery or emergency treatment, tell the doctor or dentist that you are using MONOFER.

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

Tell your doctor straight away if you:

- do not feel well while you are receiving treatment with MONOFER.

Intravenous iron preparations can cause severe allergic reactions. Tell your doctor or visit the Emergency Department immediately if you experience a severe allergic reaction (see side effects table below).

Things you should not do

Do not continue treatment with MONOFER if there is leakage around the injection site. Your doctor will need to be careful during treatment to avoid any leakage into your skin around the injection site. If a leak occurs the treatment must be stopped.

If there is any leak of MONOFER at the injection site it may cause irritation of the skin or a brown discolouration. Discolouration in other areas can also occur.

Driving or using machines

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

Looking after your medicine

- MONOFER should be stored below 30°C.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, MONOFER will be disposed of by your doctor or the hospital.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you 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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin related: • rash • soreness and swelling near the administration site • skin discolouration (may occur at the administration site or in other areas of the body) **Stomach related:** • nausea or vomiting • pain in and around the stomach or stomach cramps • indigestion, constipation or diarrhoea **Head related:** • headache • blurred vision • dizziness or light headedness • altered mental status • distorted sense of taste **Muscle and joint related:** • acute chest and/or back pain	**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
• muscle or joint pain or muscle spasm • tremor **Breathing related:** • acute chest tightness sometimes with shortness of breath **Heart related:** • fast or irregular heartbeats • low or high blood pressure **Allergy related:** • tingling or numbness • itchiness or hives on the skin **General:** • flushing or sweating • generally feeling unwell • flu-like symptoms • fever or feeling cold/shivering • infection • fatigue • hoarseness or a sore throat	

Serious side effects

Serious side effects	What to do
Head related: • seizure • loss of consciousness **Allergy related:** • rare but serious allergic reactions (anaphylactic reactions), which can involve: o persistent low blood pressure o swelling of the tongue/airway, difficulty swallowing o symptoms involving multiple parts of the body such as: ▪ heart (drop in blood pressure or chest pains) ▪ skin (itching, hives or swelling of the face, lips or other parts of the body) ▪ breathing (shortness of breath, wheezing or troubled breathing) ▪ stomach (vomiting or pain in and around the stomach) **Chest related:**	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• chest pain, which could be a sign of a potentially serious allergic reaction called Kounis syndrome	

Tell your doctor 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. Some of these side effects (abnormal blood test results including low level of phosphate in the blood and/or high levels of liver enzymes) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you 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 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 MONOFER contains

Active ingredient (main ingredient)	Each 1 mL of MONOFER contains 100 mg of iron as ferric derisomaltose
Other ingredients (inactive ingredients)	• water for injections • sodium hydroxide (to adjust pH) • hydrochloric acid (to adjust pH)

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

What MONOFER looks like

MONOFER is a dark brown, non-transparent solution supplied in a clear glass vial. It contains the active ingredient, ferric derisomaltose, as a sterile solution for injection/infusion.

MONOFER 100 mg/1 mL vial (AUST R 280666)

MONOFER 200 mg/2 mL vial (AUST R 290832)

MONOFER 500 mg/5 mL vial (AUST R 290833)

MONOFER 1000 mg/10 mL vial (AUST R 290834)

Not all presentations may be marketed.

Who distributes MONOFER

A. Menarini Australia Pty Ltd
Sydney, Australia

Medical Information: 1800 644 542

® = Registered Trademark

This leaflet was prepared in December 2025.

For the most up to date version of this leaflet, please go to www.menarini.com.au/cmi

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