Mircera®

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 Mircera?

Mircera contains the active ingredient methoxy polyethylene glycol-epoetin beta. Mircera is used to treat anaemia caused by chronic kidney disease (kidney failure).
For more information, see Section 1. Why am I using Mircera? in the full CMI.

2. What should I know before I use Mircera?

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

3. What if I am taking other medicines?

Some medicines may interfere with Mircera and affect how it works. Tell your doctor or pharmacist if you are taking any medicines, including any that you can get without a prescription or if you are unsure about any medicine.
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 Mircera?

Treatment with Mircera must be started under the supervision of a healthcare professional.
Further injections can be given by a healthcare professional or, after you have been trained, you can inject Mircera under the skin yourself (see instructions "How to self-inject Mircera".)
Mircera can be injected under the skin on the abdomen, arm or thigh or into a vein. Your doctor will decide which is best for you.
More instructions can be found in Section 4. How do I use Mircera? in the full CMI.

5. What should I know while using Mircera?

Things you should do	• Remind any doctor, dentist or pharmacist you visit or tell the surgeon or anaesthetist if you are going to have surgery that you are using Mircera. • Tell your doctor if you feel unusually tired, weak (lack of energy) or have shortness of breath as this could mean your Mircera treatment is not effective.
Things you should not do	• Do not stop using this medicine or change the dose without first checking with your doctor. • Do not let yourself run out of Mircera over the weekend or on holidays.
Driving or using machines	• Mircera is not expected to affect your ability to drive a car or operate machinery. However, be careful driving or operating machinery until you know how Mircera affects you.
Looking after your medicine	• Store in the fridge (2°C to 8°C). Do not freeze. Do not shake. Store in outer carton to protect from light • You may remove an individual dose of Mircera from the fridge and store it at room temperature (not above 30°C) for one month and on one occasion only.

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

6. Are there any side effects?

Common side effects include: back or join pain, muscle spasms, changes in blood pressure, ringing in ears, vision problems, diarrhoea, constipation, nausea, vomiting, stomach pain, indigestion, sore throat or nose, fever, cough, shortness of breath, difficulty sleeping, pain with urination, swelling of ankles, feet or hands, feel tired, itching, hot flushes. Serious side effects include blood clots in your dialysis access, bleeding or bruising more easily, chest pain, feeling of tightness in chest, headache, red skin reaction. These side effects require medical attention.
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.

Mircera® (Pronounced "meer-seh-ra")

Active ingredient(s): *methoxy polyethylene glycol-epoetin beta*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Mircera?

Mircera contains the active ingredient methoxy polyethylene glycol-epoetin beta. Mircera is used to treat anaemia caused by chronic kidney disease (kidney failure).

Anaemia is a condition caused by low levels of red blood cells, resulting in low haemoglobin, a protein that transports oxygen in the blood. Consequently your body's tissues might not receive enough oxygen. Symptoms may include tiredness, weakness and shortness of breath.

Mircera belongs to a group of medicines known as hormones. The kidneys produce the natural hormone erythropoietin, which stimulates the production of red blood cells in the bone marrow and spleen.

Like erythropoietin, Mircera works by increasing the number of red blood cells and the haemoglobin level in your blood. It will reduce your need for blood transfusions. Compared to other erythropoietin medicines, Mircera can stay in your body longer, therefore requiring fewer injections for your treatment.

Mircera is used to treat anaemia caused by chronic kidney disease. It has not been shown that Mircera can be used to treat anaemia caused by other diseases.

Your doctor, however, may have prescribed Mircera for another purpose.

Ask your doctor if you have any questions about why Mircera has been prescribed for you.

Mircera is not addictive.

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

2. What should I know before I use Mircera?

Warnings

Do not use Mircera if:

- you are allergic to methoxy polyethylene glycol-epoetin beta, any other similar medicines (i.e. containing erythropoetin) or any of the ingredients listed at the end of this leaflet.
    - Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or gives on the skin.
    - Always check the ingredients to make sure you can use this medicine.
- **You have high blood pressure that is not well controlled.**
- **The package is torn or shows signs of tampering.**
- **The expiry date (EXP) printed on the pack has passed.**

  If you take this medicine after the expiry date has passed, it may not work as well.
- **You are not sure if you should be using Mircera, talk to your doctor.**
- You are healthy or have not been prescribed Mircera. Using it can lead to too high haemoglobin levels and cause problems with the heart or blood vessels that may be life-threatening.
- **Do not give Mircera to children or adolescents under the age of 18 years.**

  The safety and effectiveness of Mircera have not been established in these patients.

Check with your doctor if you:

- **have any of the following medical conditions:**
    - Disorders associated with abnormal haemoglobin (haemoglobinopathies);
    - Blood clotting diseases, which mean you bleed or bruise more easily;
    - High blood pressure - it is important to follow your doctor's instructions to control your blood pressure, including taking blood pressure medicines and changes to your diet;
    - Cancer;
    - Epilepsy or seizures;
    - Any other illness or health problems. A number of conditions such as vitamin deficiencies may affect how well you respond to Mircera;
- **Have any allergies to any other medicines, foods, preservatives or dyes.**
- **Plan to have surgery.**
- **take any medicines for any other condition**
- **Have not told your doctor about any of the above, tell them before you start using Mircera.**

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.

- Mircera is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

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

- It is not known whether Mircera passes into breast milk. Your doctor will discuss the risks and benefits of using Mircera if you are breast-feeding.

Blood and Blood Pressure

- Your doctor will check the amount of iron in your blood before and during your Mircera treatment. If the amount is too low your doctor may recommend you take iron supplements.
- Your doctor will check your blood pressure before and during your Mircera treatment. It is important to follow your doctor's instructions to control your blood pressure, including taking blood pressure medicines and changes to your diet. If your blood pressure cannot be controlled your doctor may stop your Mircera treatment or reduce the dose.
- A condition called pure red cell aplasia (stopped or reduced production of red blood cells due to your body producing antibodies against erythropoietin) has been observed in some patients treated with erythropoietin products including Mircera. If your doctor suspects or confirms that you have these antibodies in your blood you must not be treated with Mircera.

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.

Some medicines may be affected by Mircera, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Mircera.

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

4. How do I use Mircera?

Use Mircera exactly as your doctor has prescribed.

Treatment with Mircera must be started under the supervision of a healthcare professional.

Further injections can be given by a healthcare professional or, after you have been trained, you can inject Mircera under the skin yourself (see instructions "How to self-inject Mircera".)

Mircera can be injected under the skin on the abdomen, arm or thigh or into a vein. Your doctor will decide which is best for you.

Your doctor will carry out regular blood tests that monitor your haemoglobin levels and making sure they **do not** exceed a certain level. High haemoglobin levels could put you at risk of heart or blood vessel problems which could increase the risk of death. If necessary, your dose may be changed by your doctor during therapy according to your response.

If you have not been treated with an erythropoietin medicine

If you are not currently on dialysis, the recommended starting dose of Mircera is 1.2 micrograms for every kilogram of your body weight once per month or if you prefer 0.6 micrograms for every kilogram of your body weight once every 2 weeks.

If you are currently on dialysis, the recommended starting dose of Mircera is 0.6 micrograms for every kilogram of your body weight once every 2 weeks.

Your haemoglobin level should be tested regularly. Depending on the result, your doctor may increase or decrease your Mircera dose. Dose changes should not be made more often than once a month.

Once your anaemia is corrected, your doctor may change your injection to once a month.

If you are already being treated with an erythropoietin medicine

Your doctor may replace your current medicine with Mircera.

Your doctor will calculate your Mircera starting dose based on the last dose of your previous medicine. The first Mircera dose will be given on the planned injection day of your previous medicine. Mircera will be given as a single injection once a month (or if you prefer, once every two weeks).

Your haemoglobin level should be tested regularly. Depending on the result, your doctor may increase or decrease your Mircera dose, or temporarily stop treatment. Dose changes should not be made more often than once a month.

Treatment with Mircera is normally long-term. It can however, be stopped on the advice of your doctor at any time. Continue using Mircera until your doctor tells you to stop.

When to use Mircera

- Mircera should be used as a single injection once a month (or if you prefer, once every two weeks) depending on your body weight.

How to self-inject Mircera

Your doctor may discuss with you whether it would be more convenient for you to inject Mircera yourself at home. This is a simple procedure and many patients prefer it. Always use Mircera exactly as your doctor has told you. Check with your doctor or nurse if you are unsure.

The Mircera pre-filled syringe is ready for use and can be injected by yourself either under the skin (on the abdomen, arm or thigh) or if you are on haemodialysis, through the haemodialysis vascular access according to your doctor's advice.

Each pre-filled syringe is to be used for a single injection only. **Do not** mix Mircera solution with other injectable medicines.

Setting up for an injection

Before you begin

1. Find a clean, comfortable area
2. Gather all the supplies you will need;

Included in the pack:

- A Mircera pre-filled safety syringe and a separate needle.

Not included in the pack:

- Cleansing alcohol swabs.
- Cotton wool or dry sterile pad.
- A sharps (puncture proof) disposal container.

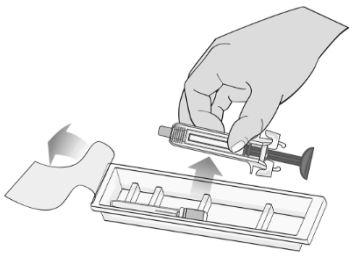
3. Remove an individual dose of Mircera from the fridge and allow it to reach room temperature. This should take about 30 minutes. **Do not** warm up the syringe in any other way.

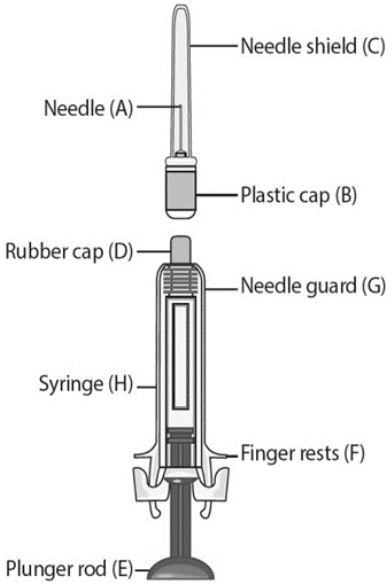
Do not shake the pre-filled syringe. If the solution has been shaken and appears foamy, **do not** use it (shaking Mircera or exposing it to light may damage the medicine). Do not use it if you have accidentally dropped the syringe. Do not attempt to take the syringe apart.

Check the expiration date stated on the outer carton and pre-filled syringe label after 'EXP' to make sure that it has not expired. The expiry date refers to the last day of that month. Do not use Mircera after the expiry date.

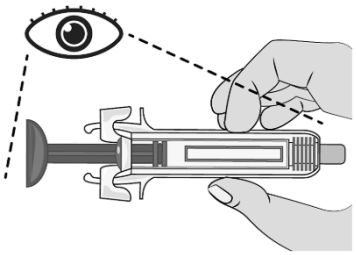
Preparing the Mircera pre-filled syringe and needle for injection

4. Wash your hands with soap and water. Cleanliness is vital during the injection procedure.
5. Take the pre-filled syringe and needle out of the blister packaging. Only handle the syringe by the body. Do not push the finger rests (F) as doing this too early will lock the needle shield, which prevents you from using your dose.

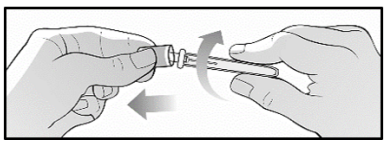




6. Only use if the solution is clear, colourless (slightly yellow in colour is acceptable) and there are no visible particles.

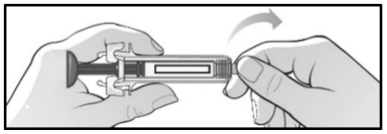


7. Grasp the needle shield (C) firmly in both hands. Remove the plastic cap (B), twist then pull.

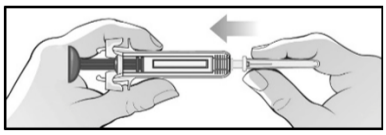


DO NOT REMOVE THE NEEDLE SHEILD (C). **DO NOT** TOUCH THE PLUNGER ROD (E) OR FINGER RESTS (F) AT THIS TIME. Doing so will release the needle guard (G) and you will be unable to inject your dose of Mircera.

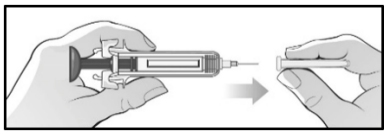
8. Remove the rubber cap (D) from the syringe (bend and pull).



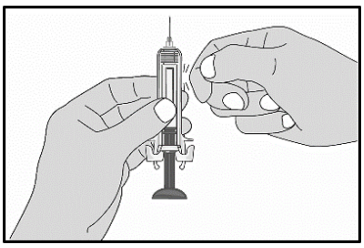
9. Attach the needle with needle shield (A and C) to the syringe (H) by pushing firmly together.



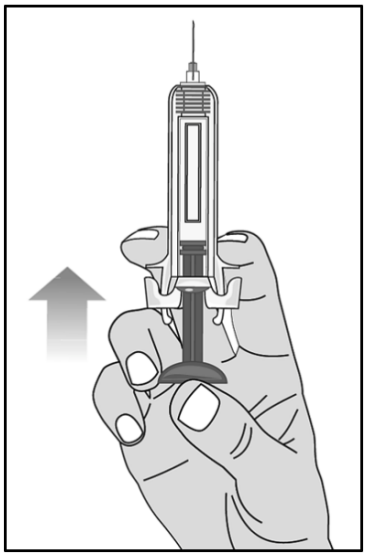
10. Remove the needle shield (C) and prepare for injection.



To remove air bubbles from the pre-filled syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring any bubbles to the top.



Push the plunger up slowly to remove all air, as shown to you by a healthcare professional.

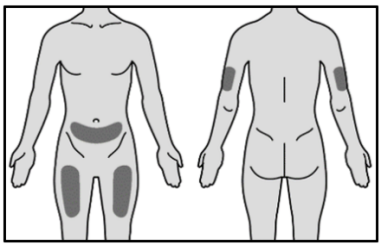


Injecting the solution

If your doctor has advised you to inject Mircera into a vein (e.g. through the haemodialysis vascular access) please administer your dose as shown by your healthcare professional.

If you have been advised to inject Mircera under your skin please follow the subsequent instructions step by step.

11. Select the injection site on the outer upper arm, abdomen (away from your navel or waistline) or thigh as shown below. The back of the upper arm is not a recommended site for self-injection. Use this injection site only if you inject someone else.



You should use a different injection site each time you administer an injection, at least three centimetres from the area you used for the previous injection.**Do not** inject areas that could be irritated by a belt or waistband.

Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

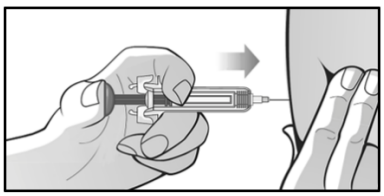
12. Clean the skin where the injection is to be made with a cleansing alcohol swab. Wait for the area to dry.

13. Hold the syringe firmly with one hand and pull off the needle shield (C) with the other hand. Throw away the needle shield in the puncture-resistant or sharps container.

Do not touch the needle or let it touch any surface, as the needle may become contaminated and may cause injury if touched.

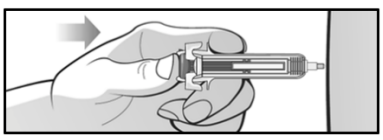
You may see a drop of liquid at the end of the needle. This is normal.

14. With one hand, pinch a fold of loose skin. Insert the needle into the pinched skin, using a quick “dart like” motion, as shown by your healthcare professional.



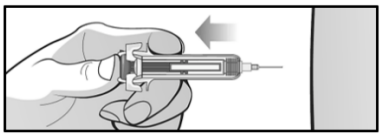
15. Slowly press the plunger rod (E) with your thumb while holding the finger rests (F), until the full dose has been given.

    Do not release the plunger rod (E).

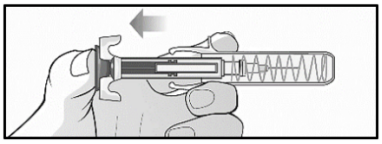


Removing the needle

16. Take the needle out of the skin without releasing the plunger rod (E).



17. Once removed, release the plunger rod (E) allowing the needle to retract into the needle guard (G).



18. Press the injection site with cotton wool or a dry sterile pad for several seconds. **Do not** massage the injection site.

19. Dispose of the syringe with the needle (protected in the needle guard (G)) in a puncture-proof (sharps) container as instructed by your doctor, nurse or pharmacist.

Never put the used syringe in your normal household garbage or recycling.

If you forget to use Mircera

Mircera should be used regularly at the same time as prescribed. If you miss your dose at the usual time, administer the missed dose as soon as you remember and speak to your doctor about when to take the next dose.

If you use too much Mircera

Please contact your doctor or pharmacist if you used too much Mircera as it may be necessary to perform some blood tests and stop your treatment temporarily.

If you think that you have used too much Mircera, 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.

Keep these telephone numbers handy.

If you are not sure what to do, contact your doctor or pharmacist.

5. What should I know while using Mircera?

Things you should do

If you are about to start any new medicine, remind your doctor and pharmacist that you are using Mircera.

Tell all doctors, dentists, and pharmacists who are treating you that you are using Mircera.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Mircera.

It may affect other medicines used during surgery.

Tell your doctor if you become pregnant while using Mircera.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that Mircera is not helping your condition.

Medicines **do not** always help every patient.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Call your doctor straight away if you:

- experience any of the serious side effects mentioned in Section 6. Are there any side effects?

Remind any doctor, dentist or pharmacist you visit that you are taking Mircera.

Things you should not do

- **Do not stop using Mircera or change the dose without first checking with your doctor.**
- **Do not let yourself run out of Mircera over the weekend or on holidays.**
- **Do not give Mircera to anyone else even if they have the same condition as you.**
- **Do not use Mircera to treat any other complaints unless your doctor tells you to.**

Blood and Blood Pressure monitoring

- **Tell your doctor that you are using Mircera if you are having any blood tests.**

Most patients' blood iron levels decrease when on erythropoietin therapy and you may need to be treated with iron supplements.

- **If you have blood pressure problems it is important to follow your doctor's instructions to control your blood pressure, including taking blood pressure medicines and changes to your diet while using Mircera.**
- **Tell your doctor if you feel unusually tired, weak (lack of energy) or have shortness of breath as this could mean your Mircera treatment is not effective. Your doctor will check that you do not have other causes of anaemia and may perform blood tests or examine your bone marrow. If you have developed pure red cell aplasia your Mircera treatment will be discontinued. You will not receive another erythropoietin and your doctor will determine the best course of action to treat your anaemia.**

Driving or using machines

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

However, Mircera is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

- **Store in the fridge (2°C to 8°C). Do not freeze. Do not shake.**
- **Do not** use a pre-filled syringe that has been frozen and **do not** expose it to temperatures above 30 C.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- **Once dispensed, take Mircera home and place in the fridge as soon as possible.**
- **You may then remove an individual dose of Mircera from the fridge and store it at room temperature (not above 30°C) for one month and on one occasion only. Once you have stored Mircera at room temperature (not above 30° C) you must not put Mircera back in the fridge. Once you have removed Mircera from the fridge you must use it within one month even if it has not passed the expiry date.**
- **Keep Mircera where young children cannot reach it.**

Follow the instructions in the carton on how to take care of your medicine properly.

When to discard your medicine

The syringe is intended for single use only and must be thrown away after the injection. Dispose of the syringe with the needle (protected in the needle guard) in a puncture proof container as instructed by your doctor, nurse or pharmacist.

Never put the used syringe in your normal household garbage.

Getting rid of any unwanted medicine

If your doctor tells you to stop using Mircera, or the pre-filled syringe has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

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
Stomach/digestion/bowel/bladder related: • Diarrhoea or constipation • Pain with urination or increased need to urinate • Nausea (feeling sick) or vomiting • Stomach pain or indigestion **Nose/throat/breathing related:** • Sore throat or nose • Cough or shortness of breath **Skin related:** • Itching • Hot flushes **Blood pressure related:** • High blood pressure symptoms include headache, dizziness, confusion, ringing in the ears (tinnitis) and vision problems • Low blood pressure symptoms include dizziness or light headedness **General body related:** • Swelling of the ankles, feet or hands • Back or joint pain or muscle spasms • Fever • Difficulty sleeping • Fatigue or unusual weakness, looking pale	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **This list includes the more common side effects of Mircera. They are usually mild and short-lived.**

Serious side effects

Serious side effects	What to do
Blood related: • Blood clots in your dialysis access. • Bleeding or bruising more easily. **General symptoms:** • Chest pain, feeling of tightness, pressure or heaviness in the chest. • Headache. • Red skin reaction that can include pimples or spots. The above list includes serious side effects that may require medical attention. Serious side effects are uncommon.	**Tell your doctor as soon as possible if you notice any of those listed.**
Blood pressure related: • Worsening of existing high blood pressure. Symptoms may include headache, especially sudden, stabbing, migraine-like headache, confusion, speech disturbances, fits or convulsions. **Allergic/skin related:** • Allergic reaction. Symptoms may include shortness of breath, wheezing or breathing difficulties, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. • Blisters on your skin, especially severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. • Severe skin reactions or rash that may cover your whole body. • Feeling unusually tired, weak (lack energy) or have shortness of breath. The above list includes very serious side effects that may require urgent medical attention or hospitalisation. These side effects are rare.	**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.**

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.

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 Mircera contains

Active ingredient (main ingredient)	Methoxy polyethylene glycol-epoetin beta
Other ingredients (inactive ingredients)	Monobasic sodium phosphate monohydrate Sodium sulfate Mannitol Methionine Poloxamer Water for injections
Potential allergens	NIL

Mircera is lactose and gluten free.

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

What Mircera looks like

Mircera solution for injection is slightly yellow to colourless and clear (no visible particles).

Mircera is available as a pack containing one single use prefilled syringe and a 27 gauge ½ inch needle The syringe plungers and packaging are coloured to easily identify the strength as follows:

30 mcg/0.3 mL (aqua)

50 mcg/0.3 mL (yellow)

75 mcg/0.3 mL (red)

100 mcg/0.3 mL (turquoise)

120 mcg/0.3 mL (lime)

200 mcg/0.3 mL (purple)

360 mcg/0.6 mL (salmon)

Australian Registration Numbers

30 mcg/0.3 mL AUST R 153810

50 mcg/0.3 mL AUST R 153813

75 mcg/0.3 mL AUST R 153801

100 mcg/0.3 mL AUST R 153806

120 mcg/0.3 mL AUST R 153807

200 mcg/0.3 mL AUST R 153805

360 mcg/0.6 mL AUST R 153804

Who distributes Mircera

Mircera is distributed in Australia by:

Roche Products Pty Limited.

ABN 70 000 132 865

Level 8, 30 - 34 Hickson Road

Sydney NSW 2000

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

This leaflet was prepared in April 2026.