

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about MIRCERA.

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 MIRCERA 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 MIRCERA IS USED FOR

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 contains the active ingredient methoxy polyethylene glycol-epoetin beta and 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.

BEFORE YOU USE MIRCERA

When you must not use it

Do not use MIRCERA if:

- 1. You have an allergy or have had a reaction in the past to:**
 - any medicine containing methoxy polyethylene glycol-epoetin beta
 - any other similar medicines (i.e. containing erythropoietin)
 - any ingredients listed at the end of this leaflet

Some symptoms of an allergic reaction 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.

2. You have high blood pressure that is not well controlled.

3. The package is torn or shows signs of tampering.

4. 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.

If you are not sure if you should be using MIRCERA, talk to your doctor.

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.

Before you start to use MIRCERA

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.

Tell your doctor if:

- 1. You are pregnant or plan 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.
- 2. You are breast-feeding or plan to breast-feed.**
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.
- 3. You have, or have had, 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;

Healthy people should not use MIRCERA. Using it can lead to too high haemoglobin levels and cause problems with the heart or blood vessels that may be life-threatening.

4. You have any allergies to any other medicines, foods, preservatives or dyes.

5. You plan to have any surgery.

If you have not told your doctor about any of the above, tell them before you start using MIRCERA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a 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.

Ask your doctor or pharmacist if you are not sure about any medicine.

HOW TO USE MIRCERA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to inject

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.

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 take 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

Remember to wash your hands!

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 the MIRCERA box from the fridge and allow it to reach room temperature. This should take about 30 minutes.

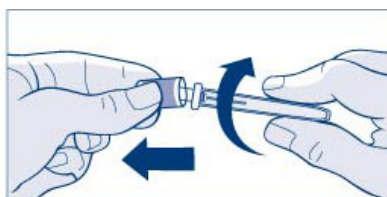
You may remove MIRCERA from the fridge and store it at room temperature (not above 30 °C) for one month on one occasion only. Once you have stored MIRCERA at room temperature (not above 30 °C) you must not put MIRCERA back in the fridge. Once you have removed MIRCERA from the fridge you must use it within one month (even if it has not passed the expiry date).

Do not use a pre-filled syringe that has been frozen and do not expose it to temperatures above 30 °C.

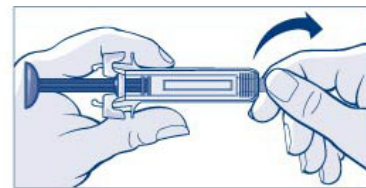
Do not shake the pre-filled syringe. If the solution has been shaken and appears foamy, do not use it (shaking MIRCERA or exposing it to light may damage the medicine)

Preparing the MIRCERA pre-filled syringe and needle for injection

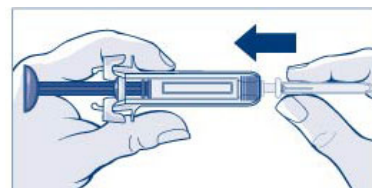
4. Take the pre-filled syringe and needle out of the blister.
5. Only use if the solution is clear, colourless (slightly yellow in colour is acceptable) and there are no visible particles.
6. Grasp the needle firmly in both hands. Break the seal of the needle, using a twisting motion and remove the plastic cap. **Do not** remove the needle guard at this time.



7. Remove the rubber tip cap from the syringe (bend and pull).

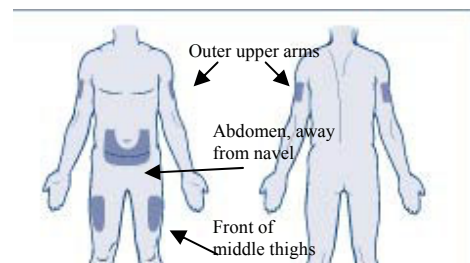


8. Attach the needle to the syringe by pushing firmly together.



Injecting the solution

9. If your doctor has advised you to inject MIRCERA into a vein, please administer your dose as shown by your healthcare professional.
10. If you have been advised to inject MIRCERA under your skin please follow the following instructions step by step.
11. Remove air bubbles from the syringe by holding the syringe with the needle pointing up. Tap the syringe gently (do not shake) to bring any bubbles to the top. Push the plunger up slowly to the correct dose, as shown to you by a healthcare professional.
12. Select the injection site on the arm, abdomen or thigh (except your navel or waistline) as shown in the following diagram.



13. Clean the skin where the injection is to be made with a cleansing alcohol swab.

Information Centre (telephone 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand) or go to Accident and Emergency at your nearest hospital. 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.

WHILE YOU ARE USING MIRCERA

Things you must 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 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.

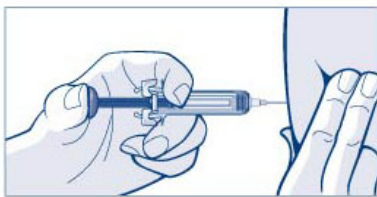
Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you have blood pressure problems it is important to follow your doctor's instructions to control your blood pressure, including taking blood pressure

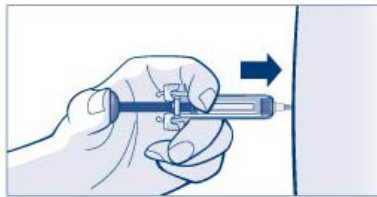


14. Wait for the area to dry. Remove the needle guard from the MIRCERA pre-filled syringe.

15. 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.

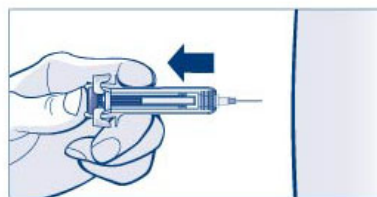


16. Slowly press the plunger while holding the finger rests, until the full dose has been given. **Do not release the plunger.**

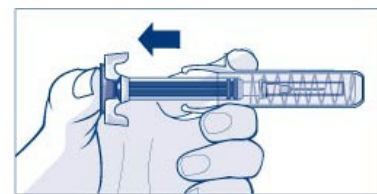


Removing the needle

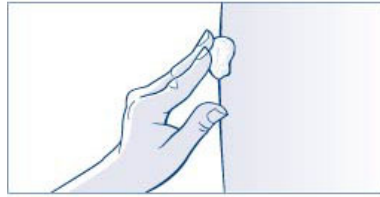
17. Take the needle out of the skin **without releasing the plunger.**



18. Once removed, release the plunger allowing the needle guard to protect the needle.



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



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



Never put the used syringe in your normal household garbage.

How long to use it

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.

If you forget to use it

If you miss a dose of MIRCERA administer the missed dose as soon as you remember and speak to your doctor about when to take the next dose.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you inject too much MIRCERA (overdose)

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 you or anyone else may have used too much MIRCERA immediately telephone your doctor, or Poisons

medicines and changes to your diet while using MIRCERA.

Tell your doctor if you feel that MIRCERA is not helping your condition. Medicines do not always help every patient.

Tell your doctor if you feel unusually tired, weak (lack 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.

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

Things you must 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 other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how MIRCERA affects you. However, MIRCERA is not expected to affect your ability to drive a car or operate machinery.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using MIRCERA.

MIRCERA generally causes few side effects and helps most people with anaemia; however it may have some unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Back or joint pain or muscle spasms.
- Changes in blood pressure; symptoms of high blood pressure include headache, dizziness, confusion, ringing in the ears (tinnitus) and vision problems. Symptoms of low blood pressure include dizziness or light headedness.
- Diarrhoea or constipation.
- Nausea (feeling sick) or vomiting.
- Stomach pain or indigestion.
- Sore throat or nose.
- Fever.
- Cough or shortness of breath.
- Difficulty sleeping.
- Pain with urination or increased need to urinate.
- Swelling of the ankles, feet or hands.
- Fatigue or unusual weakness, looking pale.
- Itching.
- Hot flushes.

The above list includes the more

common side effects of MIRCERA. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Blood clots in your dialysis access.
- Bleeding or bruising more easily.
- 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 immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Worsening of existing high blood pressure. Symptoms may include headache, especially sudden, stabbing, migraine-like headache, confusion, speech disturbances, fits or convulsions.
- 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.
- 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.

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in the lists above.

STORING MIRCERA

Storage

**Store in the fridge (2 °C – 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.

You may remove 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 may 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.

Do not use MIRCERA after the expiry date which is stated on the outer carton and pre-filled syringe label after 'EXP'. The expiry date refers to the last day of that month.

Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep MIRCERA where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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.

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.

PRODUCT DESCRIPTION

Availability

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 µg/0.3 mL (aqua)
50 µg/0.3 mL (yellow)
75 µg/0.3 mL (red)
100 µg/0.3 mL (turquoise)
120 µg/0.3 mL (lime)
200 µg/0.3 mL (purple)
360 µg/0.6 mL (salmon)

What MIRCERA looks like

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

Ingredients

Active ingredient

- Methoxy polyethylene glycol-epoetin beta

Inactive ingredients

- Sodium phosphate - monobasic, monohydrate
- Sodium sulfate
- Mannitol
- Methionine
- Poloxamer 188
- Water for injection

MIRCERA is lactose and gluten free.

Distributor

MIRCERA is distributed in Australia by:

Roche Products Pty Limited.
ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1800 233 950

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

Australian Registration Numbers

30 µg/0.3 mL Aust R 153810
50 µg/0.3 mL Aust R 153813
75 µg/0.3 mL Aust R 153801
100 µg/0.3 mL Aust R 153806
120 µg/0.3 mL Aust R 153807
200 µg/0.3 mL Aust R 153805
360 µg/0.6 mL Aust R 153804

This leaflet was prepared on 10 May 2011.