

MIRCERA®

Methoxy polyethylene glycol-epoetin beta (50µg/0.3mL, 75µg/0.3mL, 100µg/0.3mL, 120µg/0.3mL, 150µg/0.3mL, 200µg/0.3mL)

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What MIRCERA is used for

MIRCERA is a medicine used to treat anemia in certain people with chronic kidney disease (CKD). People with anemia have a lower-than-normal number of red blood cells (RBCs). MIRCERA works like the human protein called erythropoietin to help your body make more RBCs.

MIRCERA is used to treat:

- Anemia caused by CKD in adult patients, who may or may not be on dialysis
- Symptomatic anemia caused by CKD in pediatric patients (aged 3 months to less than 18 years) on erythropoiesis stimulating agent (ESA) maintenance treatment after their hemoglobin level was stabilized with the previous ESA

This medicine is prescribed to you because you have anemia caused by your CKD and associated with typical symptoms, such as tiredness, weakness and shortness of breath. This means that you have too few RBCs and your hemoglobin level is too low (your body's tissues might not receive enough oxygen).

How MIRCERA works

MIRCERA belongs to a new class of hormones, known as Continuous Erythropoietin Receptor Activators.

Erythropoietin, a natural hormone produced by the kidneys, stimulates the production of red blood cells in the bone marrow and spleen.

MIRCERA works like erythropoietin, thereby increasing the number of red blood cells and the hemoglobin level in your blood. Consequently, this will

reduce your need for blood transfusions.

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

Before you use MIRCERA

- When you must not use it

Do not take or receive MIRCERA if:

- you have or have had an allergic reaction in the past to:
 - MIRCERA (Methoxy polyethylene glycol-epoetin beta) or any ingredients listed at the end of this leaflet.
 - any other similar medicines (i.e. containing erythropoietin).
 - 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 hives on the skin
- you are diagnosed with Pure Red Cell Aplasia (PRCA) through examination of the bone marrow.
- 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.

Children and adolescents

MIRCERA can be used for the treatment of children and adolescents, 3 months of age to less than 18 years, with anemia associated with chronic kidney disease. They should be stabilized on ESA maintenance therapy prior to switching to MIRCERA and may or may not be receiving dialysis. Talk to your doctor, pharmacist or nurse before you are given this medicine if you, or your child, are under 18 years of age.

- Before you start to use it

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 to take iron supplements.

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.

Tell your doctor if:

- you are pregnant or plan to become pregnant. MIRCERA is not recommended for use during pregnancy.
- you are breastfeeding or intend to breastfeed. It is not known whether it affects your baby. Your doctor will discuss the risks and benefits of using MIRCERA while you are pregnant or breastfeeding.
- you have, or have had, any of the following medical conditions:
 - Disorders associated with abnormal hemoglobin (hemoglobinopathies).
 - Blood clotting diseases, which means you bleed or bruise more easily.
 - High blood pressure.
 - Cancer.
 - Epilepsy or seizures.
 - A number of conditions such as vitamin deficiencies (such as folic acid & vitamin B12) may affect how well you respond to MIRCERA.
- if you are allergic to any other medicines, foods, dyes or preservatives.
- you plan to have surgery.

Healthy people should not use MIRCERA. Using it can lead to hemoglobin levels which are too high, thus causing problems that may be life-threatening to the heart or blood vessels.

If you have not told your doctor about any of the above, do so before you start taking MIRCERA.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a

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prescription from a pharmacy, supermarket or health food shop.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking 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 and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to use

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, as an adult, you can inject MIRCERA yourself. Children and adolescents less than 18 years should not self-inject MIRCERA, the administration should be performed by a healthcare professional or trained adult caregiver (see instructions "**How to self-inject MIRCERA**").

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

Your doctor will carry out regular blood tests that monitor your hemoglobin levels and make sure they do not exceed a certain level. High hemoglobin 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 hemoglobin 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 anemia 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 hemoglobin 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

Important Information

- Do not use MIRCERA if the syringe, the needle, the box or the plastic tray containing the syringe appears to be damaged.
- The needle is fragile, handle it with care.

- Do not use the syringe if the contents are cloudy, hazy or contain particles.
- Never attempt to take the syringe apart.
- Never handle or pull on the syringe by its plunger.
- Do not remove the needle shield until you are ready to perform an injection.
- Do not swallow the medicine in the syringe.
- Do not inject through clothing.
- Do not reuse or resterilize the syringe or the needle.
- Keep syringe, needle and supplies out of the reach of children.

Materials included in the pack (Figure A):

- A pre-filled syringe containing MIRCERA
- A separate injection needle

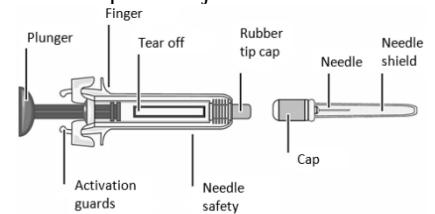


Figure A

Materials not included in the pack (Figure B):

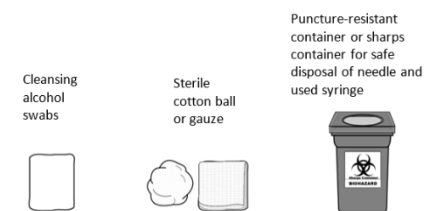


Figure B

Assemble all of the supplies you will need for an injection on a clean, well-lit flat surface such as a table.

How to Give the Injection

1. Allow the syringe to adjust to room temperature.

Carefully remove the box containing the MIRCERA pre-filled syringe from the refrigerator. Keep the syringe in the box to protect it from light and allow it to reach room temperature for at least 30 minutes (Figure C).

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- Not allowing the medicine to come to room temperature could result in an uncomfortable injection, and it may be difficult to depress the plunger.
- Do not warm up the syringe in any other way.

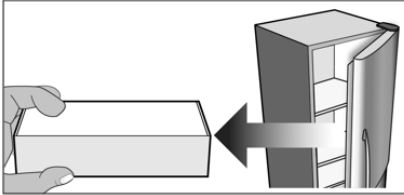


Figure C

Open the box and remove the plastic tray with the MIRCERA pre-filled syringe without peeling back the protective film (Figure D).

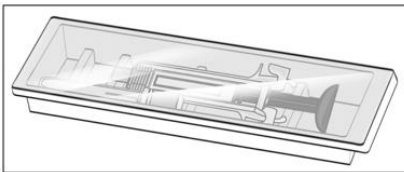


Figure D

2. Clean your hands

Disinfect your hands well with soap and water or hands sanitizer (Figure E).



Figure E

3. Unpack and visually inspect the pre-filled syringe

Peel back the protective film from the plastic tray and remove the packed needle and syringe, holding the syringe by the middle of the body without touching the activation guards (Figure F).

Only handle the syringe by the body, because any contact with the activation

guards could cause premature release of the safety device.

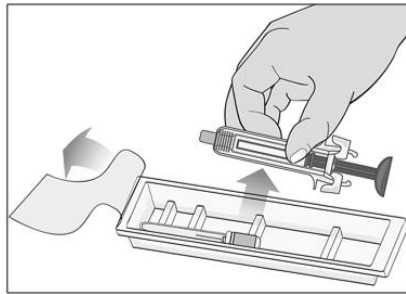


Figure F

Examine the syringe for damage and check the expiration date on the syringe and box. This is important to ensure that the syringe and medicine are safe to use (Figure G).

Do not use the syringe if:

- You have accidentally dropped the syringe.
- Any part of the syringe appears to be damaged.
- The contents are cloudy, hazy or contain particles.
- If the color is other than colorless to slightly yellowish.
- The expiration date has passed.

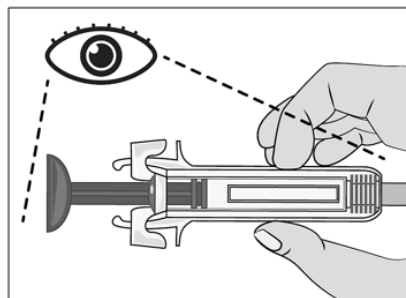


Figure G

4. Attach the needle to the syringe

Grasp the syringe in the middle of the body, hold the rubber tip cap firmly, and remove the rubber tip cap from the syringe (bend and pull) (Figure H).

- Once removed, immediately dispose of the rubber tip cap in the sharps/ puncture-resistant container.
- Do not touch the activation guards.
- Do not push the plunger.
- Do not pull on the plunger.

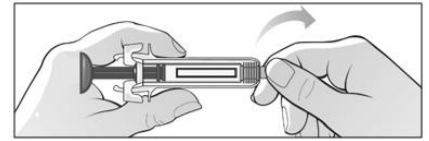


Figure H

Grasp the packaged needle firmly in both hands and examine the packaged needle for damage. Break the seal of the needle, using a twisting motion, and remove the needle cap (Figure I). Immediately throw away the needle cap in the sharps/ puncture-resistant container or sharps container. Do not remove the needle shield that protects the needle.

Do not use the needle if:

- You have accidentally dropped the needle.
- Any part of the needle appears to be damaged.

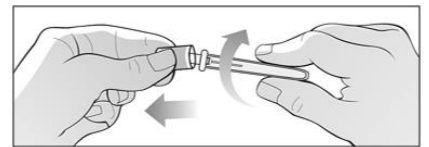


Figure I

Attach the needle to the syringe by pushing it firmly straight onto the syringe and by twisting or turning it slightly (Figure J).

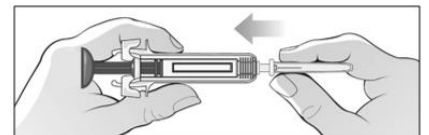


Figure J

5. Remove the needle shield and prepare for injection

Hold the syringe firmly with one hand in the middle of the body and pull the needle shield straight off with the other hand. Throw away the needle shield in the sharps/ puncture-resistant container or sharps container (Figure K).

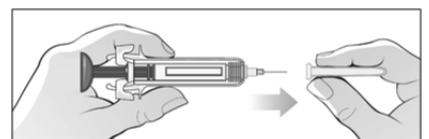


Figure K

- Once the needle shield is removed do not touch the needle or let it touch any surface, as the needle

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may become contaminated and may cause injury and pain if touched.

- You may see a drop of liquid at the end of the needle. This is normal.
- Never reattach the needle shield after removal.

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 (Figure L and M).

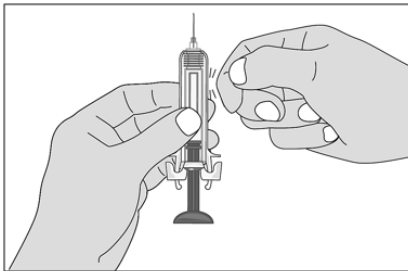


Figure L

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

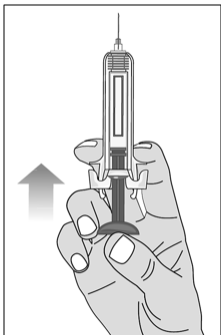


Figure M

6. Perform the injection

There are two different ways (routes) to inject MIRCERA into your body. Follow the recommendations of your healthcare professional about how you should inject MIRCERA.

Subcutaneous Route

If you are advised to inject MIRCERA under your skin, please administer your dose as described below.

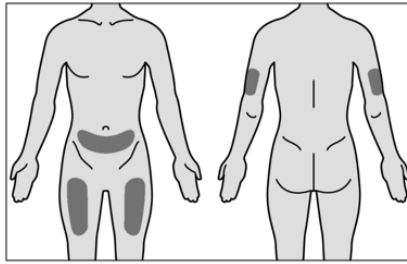


Figure N

Choose one of the recommended injection sites as shown. You may inject MIRCERA into the upper arm, thigh or abdomen, but not in the area around the navel (belly button) (Figure N). The back of the upper arm is not a recommended site for self-injection. Use this injection site only if you inject someone else. When selecting an injection site:

- You should use a different injection site each time you administer an injection, at least three centimeters from the area you used for the previous injection.
- Do not inject into 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.

Clean the chosen injection site area using an alcohol pad to reduce the risk of infection; carefully follow the instructions of the alcohol pad (Figure O).



Figure O

- Let the skin dry for approximately 10 seconds.
- Be sure not to touch the cleaned area prior to the injection and do not fan or blow on the clean area.
- Immediately throw away the alcohol pad.

Adopt a comfortable posture before performing an injection of MIRCERA.

To be sure the needle can be inserted correctly under the skin, use your free hand to pinch a fold of loose skin at the clean injection site. Pinching the skin is

important to ensure that you inject under the skin (into fatty tissue) but not any deeper (into muscle).

Injection into muscle could result in an uncomfortable injection (Figure P).

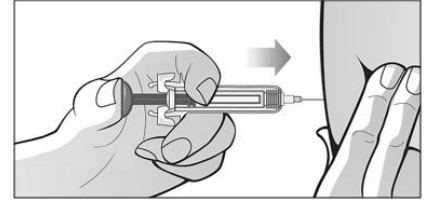


Figure P

Carefully fully insert the needle into the skin at an angle of 90° in a quick, “dart-like” motion. Then keep the syringe in position and let go of the pinch of skin.

Do not move the needle while it is inserted in the skin.

Once the needle is fully inserted into the skin, slowly push the plunger with your thumb while holding the syringe with the forefinger and the middle finger against the finger grips until all the medicine is injected. The plunger rod should be fully pushed down (depressed) and you should hear a click indicating the activation of the needle guard (Figure Q).

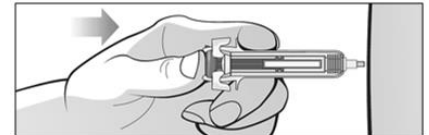


Figure Q

Do not release the plunger before the end of injection or before the plunger is completely depressed.

Take the needle out of the skin WITHOUT releasing the plunger (Figure R).

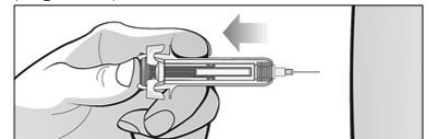


Figure R

Release the plunger, allowing the needle guard to protect the needle (Figure S).

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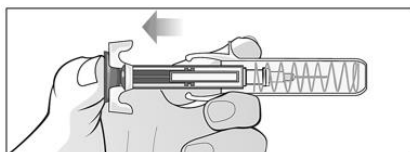


Figure S

Now, the tear-off label can be removed, if necessary (Figure T).

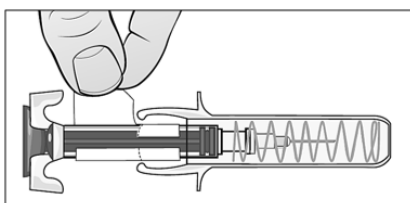


Figure T

After the injection:

- Place a sterile cotton ball or gauze over the injection site and press for several seconds. Immediately throw away the cotton ball or the gauze after use.
- Do not rub the injection site with a dirty hand or cloth.
- If needed, you may cover the injection site with a small bandage.

Dispose of the syringe:

- Throw away used syringes in a sharps/ puncture-resistant container.
- Dispose of the full sharps/ puncture resistant container.
- Do not try to replace the needle shield on the needle.
- Do not throw away the used syringe with the needle in household trash. Dispose in sharps / puncture-resistant container and/or according to health institutions policies.
- Do not reuse or resterilize the syringe and the needle.

Intravenous Route

If your healthcare professional has recommended injection of MIRCERA into a vein, you should follow the procedure described below.

After preparation of the syringe as described in steps 1 to 5:

Clean the venous port of the hemodialysis tubing with an alcohol swab as instructed by the provider or manufacturer. Immediately throw away the alcohol swab after use.

Insert the needle of the pre-filled syringe into the cleaned venous port (Figure U).

Do not touch the injection site of the venous port.

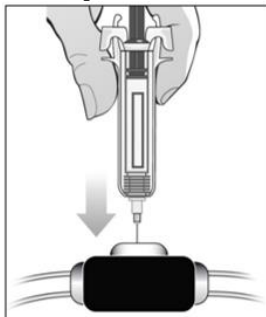


Figure U

Push the plunger with the thumb while holding the syringe with the forefinger and the middle finger against the finger grips until all the medicine is injected (Figure V).

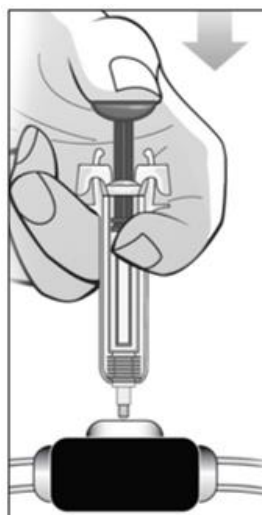


Figure V

Remove the pre-filled syringe from the venous port WITHOUT releasing the plunger.

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

Now, the tear-off label can be removed if necessary (See Figure T).

7. Dispose of the used syringe with the needle

- Throw away used syringes in a sharps/ puncture-resistant container.

- Dispose of the full sharps / puncture resistant container.
- Do not try to replace the needle shield on the needle.
- Do not throw away used syringe with the needle in household trash. Dispose in sharps / puncture-resistant container and/or according to health institutions policies.
- Do not reuse or resterilize the syringe and the needle.

- When to use it

Your doctor will tell you how often to use this medicine. Injecting MIRCERA at the same time of the day will help you remember your injections.

- How long to use it

Treatment with MIRCERA is normally long-term. 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 use too much (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.

In the case of excessive hemoglobin levels, MIRCERA should be temporarily withheld.

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, undergo any surgery, or perform any blood test, remind your doctor, dentist and pharmacist that you are using MIRCERA.

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.

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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 making changes to your diet while using MIRCERA.

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 any other complaints unless your doctor tells you 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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- Back or joint pain or muscle spasms
- Change 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
- Diarrhea or constipation
- Nausea (feeling sick) 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 head to the Accident and Emergency department 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
- Severe skin reaction: skin reddening, blister, rash, fever, sore throat or eye irritation.
- 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 hospitalization. These side effects are rare.

Other side effects not listed above may occur in some people and there may be some side effects not yet known.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MIRCERA

- Storage

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 it 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 removed MIRCERA from the fridge, it may not be put back and you must use it within one-month even if the expiry date has not passed.

Do not use MIRCERA after the expiry date which is stated on the outer carton and the 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 the bathroom or near a sink. Do not leave it on a window sill or in the car. 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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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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.

Product Description

MIRCERA is available as a pack containing one single use prefilled syringe and a 27 gauge 1/2-inch needle. Pre-filled syringes are not designed for administration of partial doses.

These are the strengths available:

- 50 mcg/0.3 mL
- 75 mcg/0.3 mL
- 100 mcg/0.3 mL
- 120 mcg/0.3 mL
- 150mcg/0.3 mL
- 200 mcg/0.3 mL

- What it 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 sulphate
- Mannitol
- Methionine
- Poloxamer 188
- Water for injection

- MAL number(s):

- MIRCERA PFS 50mcg/0.3mL
MAL20081745ARZ
- MIRCERA PFS 75mcg/0.3mL
MAL20081747ARZ
- MIRCERA PFS 100mcg/0.3mL
MAL20081746ARZ
- MIRCERA PFS 120mcg/0.3mL
MAL20091886ARZ
- MIRCERA PFS 150mcg/0.3mL
MAL20081748ARZ
- MIRCERA PFS 200mcg/0.3mL
MAL20081749ARZ

Manufacturer

Made for F. Hoffmann-La Roche Ltd.,
Basel, Switzerland

by F. Hoffmann-La Roche Ltd.,
Wurmisweg 4303 Kaiseraugst,
Switzerland
and

Release of finished drug product
by Roche Diagnostics GmbH,
Sandhofer Strasse 116, 68305
Mannheim, Germany

Product Registration Holder

Roche (Malaysia) Sdn. Bhd.
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Persiaran Lagoon, Bandar Sunway,
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Selangor, Malaysia.

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