

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIRCERA

50 micrograms/0.3 ml solution for injection in pre-filled syringe
75 micrograms/0.3 ml solution for injection in pre-filled syringe
100 micrograms/0.3 ml solution for injection in pre-filled syringe
150 micrograms/0.3 ml solution for injection in pre-filled syringe
200 micrograms/0.3 ml solution for injection in pre-filled syringe
250 micrograms/0.3 ml solution for injection in pre-filled syringe
400 micrograms/0.6 ml solution for injection in pre-filled syringe
600 micrograms/0.6 ml solution for injection in pre-filled syringe
800 micrograms/0.6 ml solution for injection in pre-filled syringe

methoxy polyethylene glycol-epoetin beta

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet :

1. What MIRCERA is and what it is used for
2. Before you use MIRCERA
3. How to use MIRCERA
4. Possible side effects
5. How to store MIRCERA
6. Further information

1. WHAT MIRCERA IS AND WHAT IT IS USED FOR

This medicine is prescribed to you because you have anaemia. This means that you have too few red blood cells and your haemoglobin level is too low (your body's tissues might not receive enough oxygen). The symptoms may be fatigue, weakness and shortness of breath.

MIRCERA is a medicine produced by gene-technology. The active ingredient is methoxy polyethylene glycol-epoetin beta. Like the natural hormone erythropoietin, MIRCERA increases the number of red blood cells and haemoglobin level in your blood.

Compared to other similar medicines called erythropoiesis stimulating agent (or ESA). MIRCERA can stay in your body longer, therefore fewer injections are required for your treatment.

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

2. BEFORE YOU USE MIRCERA

Do not use MIRCERA

- if you are allergic (hypersensitive) to methoxy polyethylene glycol-epoetin beta or to any of the other ingredients of MIRCERA (see section 6)
- if you have high blood pressure that cannot be controlled

Take special care with MIRCERA

Before treatment with MIRCERA

- A condition called Pure Red Cell Aplasia (stopped or reduced production of red blood cells) due to anti-erythropoietin antibodies was observed in some patients treated with ESAs. If your doctor suspects or confirms that you have these antibodies in your blood you must not be treated with MIRCERA.
- If you are a cancer patient be aware that ESAs and MIRCERA may act as growth factors. Please discuss this with your doctor.
- It is not known if MIRCERA has a different effect in patients with hemoglobinopathies (disorders associated with abnormal haemoglobin), severe liver disease, past or present bleeding, seizures or have a high blood platelet count. If you have any of these conditions your doctor will discuss it with you and must treat you with caution.
- 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.

During treatment with MIRCERA

- Your doctor may initiate treatment with MIRCERA if your haemoglobin level is 10 g/dl (6.21 mmol/l) or less. After initiation of therapy, your doctor will maintain your haemoglobin level between 10 and 12 g/dl (7.45 mmol/l).

Your doctor will check the amount of iron in your blood before and during MIRCERA treatment. If the amount is too low your doctor may give you an additional iron therapy.

- Your doctor will check your blood pressure before and during your MIRCERA treatment. If your blood pressure is high and cannot be controlled either by medicine or a special diet, your doctor will interrupt your MIRCERA treatment or reduce the dose.
- Your doctor will check that your haemoglobin does not exceed a certain level as high haemoglobin could put you at risk of having a problem of the heart or the blood vessels and could increase risk of death.
- Contact your doctor if you feel tired, weak or have shortness of breath as this could mean that 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 ESA and your doctor will treat you for this condition.

Children and adolescents

Treatment with MIRCERA is not recommended in children and adolescents as it has not been studied in these patients.

Important information about some of the ingredients of MIRCERA

This medicine contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially 'sodium-free'.

Using other medicines

Please tell your doctor or pharmacist if you are using, or have recently used, any other medicines, including medicines obtained without a prescription.

No interaction studies have been performed. There is no evidence that MIRCERA interacts with other medicines.

Using MIRCERA with food and drink

Food and drink do not affect MIRCERA.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

MIRCERA has not been studied in pregnant or breast-feeding women.

Tell your doctor if you are pregnant, think you are pregnant or intend to become pregnant. Your doctor will consider what is the best treatment for you during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will advise if you should stop or continue breast-feeding and stop or continue your treatment.

Driving and using machines

MIRCERA does not affect your ability to drive and use machines.

3. HOW TO USE MIRCERA

Always use MIRCERA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 yourself (see instructions at the end of this leaflet.)

MIRCERA can be injected under the skin in 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 to monitor how your anaemia is responding to treatment by measuring your haemoglobin level.

- If you are not currently treated with an ESA

The recommended starting dose of MIRCERA is 0.6 micrograms for every kilogram of your body weight. The dose is to be administered once every 2 weeks as a single injection.

Your doctor may increase or decrease your dose or temporarily stop your treatment to adjust your haemoglobin level, as appropriate for you. Dose changes will not be made more often than once a month.

Once your anaemia is corrected your doctor may change your dosing to once a month administration.

- If you are currently being treated with an ESA

Your doctor may replace your current medicine with MIRCERA. Your doctor will decide to treat you with MIRCERA administered as a single injection once a month. 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.

Your doctor may increase or decrease your dose or temporarily stop your treatment to adjust your haemoglobin to an appropriate level for you. Dose changes will not be made more often than once a month.

If you use more MIRCERA than you should

Please contact your doctor or pharmacist if you used too large a dose of MIRCERA as it may be necessary to perform some blood tests and interrupt your treatment.

If you forget to use MIRCERA

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

If you stop using MIRCERA

Treatment with MIRCERA is normally long-term. It can, however, be stopped on the advice of your doctor at any time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MIRCERA can cause side effects, although not everybody gets them.

A common side effect (occurring in less than 1 out of 10 patients) is high blood pressure.

Uncommon side effects (occurring in less than 1 out of 100 patients) are:

- headache
- vascular access thrombosis (blood clots in your dialysis access).

Rare side effects (less than 1 in 1000 patients) are:

- hypertensive encephalopathy (very high blood pressure that can result in headache, especially sudden, stabbing, migraine-like headache, confusion, speech disturbances, fits or convulsions).
If you have these symptoms please contact your doctor immediately to receive treatment.
- maculo-papular rash (red skin reaction that can include pimples or spots)
- hot flush
- hypersensitivity (severe allergic reaction that can cause unusual wheezing or difficulty in breathing; swollen tongue, face or throat, or swelling around the injection site, or make you feel light-headed, faint or cause you to collapse). If you have these symptoms please contact your doctor immediately to receive treatment.

During clinical studies patients had a slight decrease in their platelet blood counts. Some patients had platelet counts below the normal range.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MIRCERA

Keep out of the reach and sight of children.

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.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

You may remove MIRCERA from the refrigerator and store it at room temperature (not above 25 °C) for a period of one month and on one occasion only. Once you have removed your medicine from the refrigerator you must use it within this period of one month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What MIRCERA contains

- The active substance is methoxy polyethylene glycol-epoetin beta. 0.3 ml or 0.6 ml (one pre-filled syringe) contains 50, 75, 100, 150, 200, 250 micrograms or 400, 600, 800 micrograms.
- The other ingredients are sodium dihydrogen phosphate monohydrate, sodium sulphate, mannitol (E421), methionine, poloxamer 188 and water for injections.

What MIRCERA looks like and contents of the pack

MIRCERA 0.3 ml or 0.6 ml is a solution for injection in pre-filled syringe.

The solution is clear, colourless to slightly yellowish and free of visible particles.

MIRCERA comes in pre-filled syringes with laminated plunger stopper and tip cap with one needle 27G1/2. Each pre-filled syringe contains 0.3 ml or 0.6 ml. One pack contains 1 pre-filled syringe.

Marketing Authorisation Holder

Roche Registration Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

Manufacturer

Roche Diagnostics GmbH
Sandhoferstrasse 116
D-68305 Mannheim
Germany

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

N.V. Roche S.A.
Tél/Tel: +32 (0) 2 525 82 11

Luxembourg/Luxemburg

(Voir/siehe Belgique/Belgien)

: +359 2 818 44 44

Magyarország

Roche (Magyarország) Kft.
Tel: +36 - 23 446 800

Ceská republika

Roche s. r. o.
Tel: +420 - 2 20382111

Malta

(See United Kingdom)

Danmark

Roche a/s
Tlf: +45 - 36 39 99 99

Nederland

Roche Nederland B.V.
Tel: +31 (0) 348 438050

Deutschland

Roche Pharma AG
Tel: +49 (0) 7624 140

Norge

Roche Norge AS
Tlf: +47 - 22 78 90 00

Eesti

Roche Eesti OÜ
Tel: + 372 - 6 177 380

Österreich

Roche Austria GmbH
Tel: +43 (0) 1 27739

da

Roche (Hellas) A.E.
: +30 210 61 66 100

Polska

Roche Polska Sp.z o.o.
Tel: +48 - 22 345 18 88

España

Roche Farma S.A.
Tel: +34 - 91 324 81 00

Portugal

Roche Farmacêutica Química, Lda
Tel: +351 - 21 425 70 00

France

Roche

Tél: +33 (0) 1 46 40 50 00

Ireland

Roche Products (Ireland) Ltd.

Tel: +353 (0) 1 469 0700

Ísland

Roche a/s

c/o Icepharma hf

Sími: +354 540 8000

Italia

Roche S.p.A.

Tel: +39 - 039 2471

K p

G. .Stap t & S a td.

: +357 - 22 76 62 76

Latvija

Roche Latvija SIA

Tel: +371 - 7 039831

Lietuva

UAB "Roche Lietuva"

Tel: +370 5 2546799

România

Roche România S.R.L.

Tel: +40 21 206 47 01

Slovenija

Roche farmacevtska družba d.o.o.

Tel: +386 - 1 360 26 00

Slovenská republika

Roche Slovensko, s.r.o.

Tel: +421 - 2 52638201

Suomi/Finland

Roche Oy

Puh/Tel: +358 (0) 10 554 500

Sverige

Roche AB

Tel: +46 (0) 8 726 1200

United Kingdom

Roche Products Ltd.

Tel: +44 (0) 1707 366000

This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>.

HOW TO SELF INJECT MIRCERA

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 self-injected by yourself either under the skin or if you are on haemodialysis, through the haemodialysis line according to your doctor's advice. The pre-filled syringe does not contain any preservative and is to be used for one single injection only. More than one dose must not be administered per pre-filled syringe.

Do not mix the solution with other injectable medicines. Store the pre-filled syringe in the outer carton box.

Safety tips

Remove the pre-filled syringe from the refrigerator and allow it to reach room temperature in its outer carton box. This should take about 30 minutes after the package has been removed from the fridge.

Make sure that the pre-filled syringe has not been removed from the fridge for more than a single period or for longer than 1 month.

Do not use a pre-filled syringe that has been frozen and do not expose it to temperatures above 25°C.

Do not use a pre-filled syringe after the expiry date stated on the label.

Only use the pre-filled syringe if the solution is clear, colourless (slightly yellow in colour is acceptable) and is free of visible particles.

Do not shake the pre-filled syringe.

When handling the syringe, do not touch the needle.

Getting started

Assemble all of the supplies you will need for an injection on a clean surface:

Included in the pack:

A pre-filled syringe of MIRCERA and a separate injection needle

Not included in the pack:

Cleansing alcohol swabs

Sterile gauze

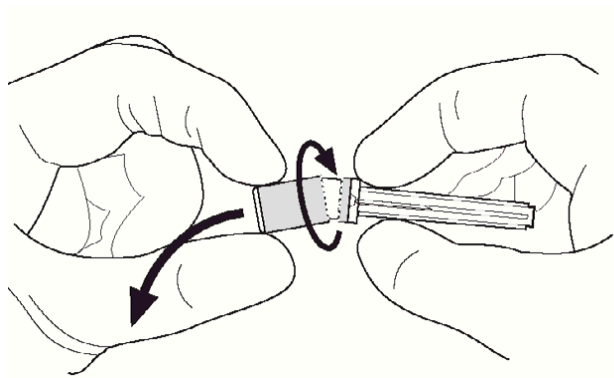
A container for the waste material

The following instructions explain how to use MIRCERA pre-filled syringes to inject yourself. Please read the instructions carefully and follow them step by step.

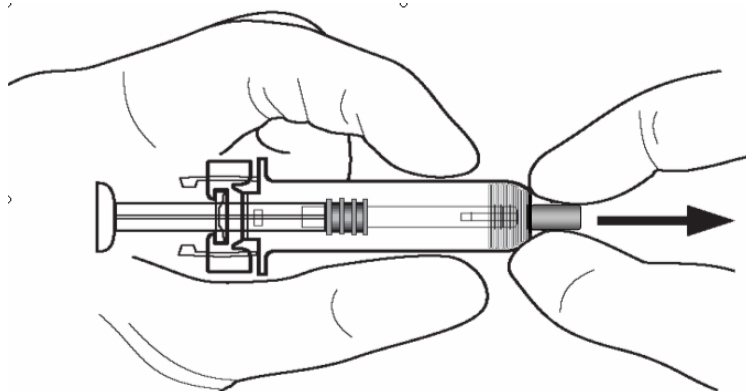
Wash your hands thoroughly before you start.

Preparing the MIRCERA pre-filled syringe and the needle for injection

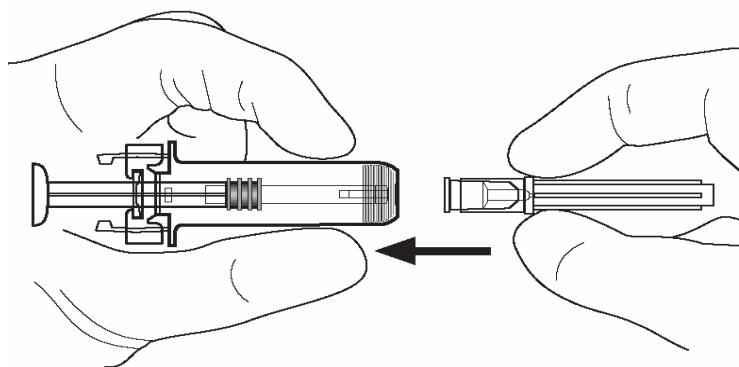
Take the pre-filled syringe and the needle out of the blister



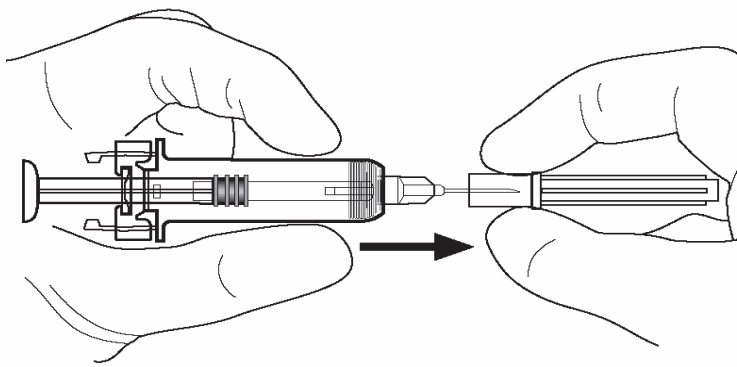
Picture 1. Break the seal and remove the plastic cap from the back of the needle. Do not remove the needle guard at this time.



Picture 2. Remove the syringe tip cap



Picture 3. Attach the needle to the syringe



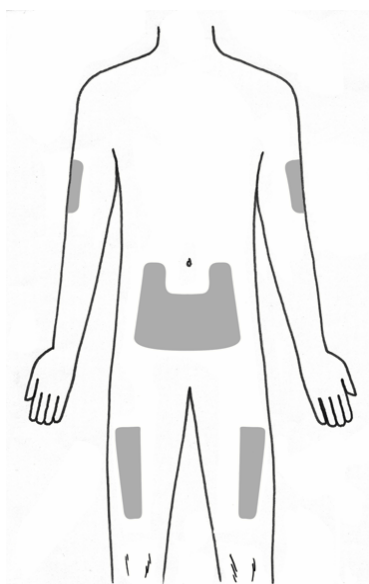
Picture 4. Remove the needle guard

Injecting the solution

If your doctor has advised you to inject MIRCERA through the haemodialysis line or into a vein, please administer your dose as shown by your health care professional.

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

To remove air bubbles from the 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 the correct dose, as shown to you by a health care professional.

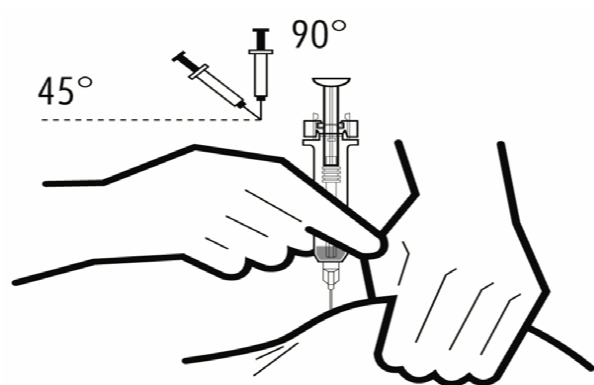


Picture 5. Select the injection site in the arm, abdomen or thigh (except your navel or waistline)

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

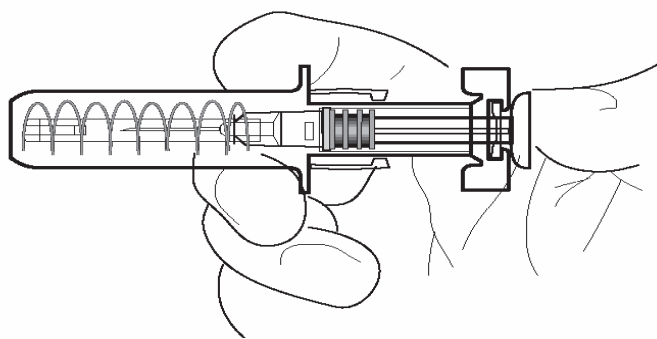
Wait for the area to dry.

With one hand, pinch a fold of loose skin. Insert the needle into the pinched skin, holding the syringe like a pencil, use a quick “dart like” motion to insert the needle either straight up and down (90 degrees angle) or at a slight angle (45 degrees angle) into the skin, as shown by your health care professional.



Picture 6. Press plunger while holding the finger rests until the full dose has been given.

Removing the needle



Picture 7. Only once the full dose has been given, release the plunger fully. The entire needle will be removed automatically from the skin and safely guarded.

Press the injection site with a small bandage or sterile gauze for several seconds.
Do not massage the injection site.
Any bleeding may be covered with an adhesive bandage.

Disposal

The syringe is intended for single use and must be thrown away after the injection. Dispose off the syringe in a closed container.