PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Mircera® 30 µg/0,3 mℓ Injection

Mircera® 50 µg/0,3 mℓ Injection

Mircera® 75 µg/0,3 mℓ Injection

Mircera® 100 µg/0,3 mℓ Injection

Mircera® 120 µg/0,3 mℓ Injection

Mircera® 150 µg/0,3 mℓ Injection

Mircera® 200 µg/0,3 mℓ Injection

Mircera® 250 µg/0,3 mℓ Injection

Mircera® 360 µg/0,6 mℓ Injection

methoxy polyethylene glycol-epoetin beta

Read all of this leaflet carefully before you start using Mircera

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Mircera has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MIRCERA is and what it is used for
2. What you need to know before you use MIRCERA
3. How to use MIRCERA
4. Possible side effects
5. How to store MIRCERA

6. Contents of the pack and other information

1. What Mircera is and what it is used for

Mircera is prescribed for you because you have anaemia due to chronic renal impairment. 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 increases the number of red blood cells and haemoglobin level in your blood.

Mircera is used to treat the 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. What you need to know before you use Mircera

Only limited data on the safety and efficacy of Mircera in children less than 18 years of age is available, therefore you must not use Mircera if you are younger than 18 years of age.

Do not use Mircera

- if you are hypersensitive (allergic) to methoxy polyethylene glycol-epoetin beta

or to any of the other ingredients of Mircera,

- if you have high blood pressure that is not controlled.
- if you are pregnant or breastfeeding your baby

Before treatment with Mircera

A condition called Pure Red Cell Aplasia (PRCA, i.e. stopped or reduced production of red blood cells) due to anti-erythropoietin antibodies was observed in some patients treated with Mircera. If your doctor suspects or confirms that you have these antibodies in your blood you must not be treated with Mircera

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,

- 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 orreduce the dose,
- your doctor will check that your haemoglobin does not exceed 11 g/dℓ, as high haemoglobin could put you at risk of having a problem of the heart or the bloodvessels and could increase risk of thrombosis (clotting), including pulmonary embolism, myocardial infarction (heart attack), stroke and 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 there is only limited data in these patients.

Take special care with Mircera:

If you are a patient with hepatitis C and you receive interferon and ribavirin

You should discuss this with your doctor because a combination of ESAs with interferon and ribavirin has led to a loss of effect and development of a condition called Pure Red Cell Aplasia (PRCA), a severe form of anaemia in rare cases. S are not approved in the management of anaemia associated with hepatitis C.

Drug abuse and dependence: If you misuse Mircera and take it when you don’thave anaemia, you

could have excessive levels of haemoglobin in your blood which can cause life threatening complications to your heart and blood systems.

Pregnancy and Breastfeeding

You should not take Mircera while you are pregnant. If you are being treated with Mircera you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking Mircera

Driving and using machinery

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

Important information about some of the ingredients of Mircera

Mircera contains mannitol and may have a laxative effect.

Other medicines and Mircera

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.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

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.

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.

Your doctor will decide on the dose that is most suitable for you.

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.

If you use more Mircera than you should

Do not share medicines prescribed for you with another person.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 dose.

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 Mircera, ask your doctor or pharmacist.

4. Undesirable side effects

Mircera can cause side effects.

Not all side effects reported for Mircera are included in this leaflet. Should yourgeneral health worsen or if you experience any untoward effects while taking Mircera, consult your doctor, pharmacist or other healthcare professional for advice.

Hypersensitivity reactions, including cases of anaphylactic reaction, have been reported.

Cases of thrombosis, including pulmonary embolism, have been reported in the post-marketing setting.

Common side effects: high blood pressure

Uncommon side effects

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

Rare side effects:

- 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 flushes,
- 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 inform your doctor or pharmacist.

As with other ESAs, cases of thrombosis, including pulmonary embolism, have been reported in the post-marketing setting.

A condition called Pure Red Cell Aplasia (PRCA, stopped or reduced production of red blood cells) due to anti-erythropoietin antibodies was observed in some patients treated with ESAs, including MIRCERA.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine.

Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Report Form", found online under SAHPRA's publications:https://www.sahpra.org.za/Publications/Index/8

5. How to store Mircera

Store all medicines out of reach 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. Do not shake the pre-filled syringe.

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 30 °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. Contents of the pack and other information

What Mircera contains

Mircera pre-filled syringes are available as single packs: 0,3 mℓ or 0,6 mℓ (360 µg) clear and colourless to slightly yellowish solution in a colourless glass pre-filled syringe with laminated grey plunger stopper and grey tip cap, and 27G1/2 needle.

The sterile needle is for single use only and is in a sealed plastic casing. The pre- filled syringe and needle are blistered as a single unit.

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

Not all product strengths may be marketed.

What Mircera looks like and contents of the pack

Mircera is a solution for injection in pre-filled syringes: the solution is clear and colourless to slightly yellowish

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E , Vorna Valley,
Midrand,
Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

8. REGISTRATION NUMBERS

Mircera 30 µg/0,3 mℓ Injection - 43/8.3/0941

Mircera 50 µg/0,3 mℓ Injection - 42/8.3/0480

Mircera 75 µg/0,3 mℓ Injection - 42/8.3/0481

Mircera 100 µg/0,3 mℓ Injection - 42/8.3/0482

Mircera 120 µg/0,3 mℓ Injection - 43/8.3/0942

Mircera 150 µg/0,3 mℓ Injection - 42/8.3/0483

Mircera 200 µg/0,3 mℓ Injection - 42/8.3/0484

Mircera 250 µg/0,3 mℓ Injection - 42/8.3/0485

Mircera 360 µg/0,6 mℓ Injection - 43/8.3/0943

9. Date of first authorisation/renewal of the authorisation

Date of registration: 05 March 2009 - Mircera 50, 75, 100, 150, 200, 250 µg;

25 November 2011 - Mircera 30, 120, 360 µg.

Last Revision: 07 December 2022

Botswana S2 BOT1202166/7/8/9
Namibia NS2 10/30.4/0088/9/90/1/2/3
Zimbabwe PP 2014/10.1/4835/6/7