PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF MEDICINE

Mircera 30 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 50 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 75 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 100 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 120 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 150 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 200 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 250 micrograms/0.3 ml solution for injection in pre-filled syringe

Mircera 360 micrograms/0.6 ml solution for injection in pre-filled syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mircera 30 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 30 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 100 micrograms/ml

Mircera 50 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 50 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 167 micrograms/ml.

Mircera 75 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 75 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 250 micrograms/ml.

Mircera 100 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 100 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 333 micrograms/ml.

Mircera 120 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 120 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 400 micrograms/ml.

Mircera 150 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 150 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 500 micrograms/ml.

Mircera 200 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 200 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 667 micrograms/ml

Mircera 250 micrograms/0.3 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 250 micrograms of methoxy polyethylene glycol-epoetin beta* at a concentration of 833 micrograms/ml.

Mircera 360 micrograms/0.6 ml solution for injection in pre-filled syringe

One pre-filled syringe contains 360 micrograms of methoxy polyethylene glycol-epoetin beta*at a concentration of 600 micrograms/ml.

The strength indicates the quantity of the protein moiety of the methoxy polyethylene glycol-epoetin beta molecule without consideration of the glycosylation.

Protein produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells and covalently conjugated to a linear methoxy-polyethylene glycol (PEG).

The potency of methoxy polyethene glycol-epoetin beta should not be compared to the potency of another pegylated or non-pegylated protein of the same therapeutic class. For more information, see section 5.1.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe (injection).

The solution is clear and colourless to slightly yellowish.

4 4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Mircera is indicated for the treatment of anaemia associated with chronic kidney disease (CKD) in adult patients. (see section 5.1).

4.2 Posology and method of administration

Mircera should not be mixed with other products.

Mircera is a sterile but unpreserved product. Do not administer more than one dose per pre-filled syringe or vial.

Any unused product remaining in the pre-filled syringe or vial should be discarded.

Only solutions which are clear, colourless to slightly yellowish and free of visible particles must be injected.

Do not shake. Allow the product to reach room temperature before injecting.

Standard dosage

Treatment with Mircera has to be initiated under the supervision of a medical doctor.

Treatment of anaemic patients with chronic kidney disease

The solution can be administered subcutaneously (SC) or intravenously (IV), according to clinical preference.

Mircera can be injected subcutaneously in the abdomen, arm or thigh. All three injection sites are equally suitable for subcutaneous injection with Mircera.

It is recommended that haemoglobin is monitored every two weeks until stabilised, and periodically thereafter.As recommended in current guidelines, the rate of increase in Hb and the target Hb should be determined for each patient individually. In CKD patients, the aim of treatment is to reach a target Hb level of 10 - 12 g/dL. Patients should be monitored closely to ensure that the lowest effective dose of Mircera is used to provide adequate control of the symptoms of anaemia.

Patients currently not treated with an Erythropoiesis Stimulating Agent (ESA):

Patients not on dialysis- In order to increase the haemoglobin to greater than, 10 g/dℓ (6,21 mmol/L) the recommended starting dose is 1,2 µg/kg body weight administered once every month as a single subcutaneous injection. Alternatively, a starting dose of 0,6 µg/kg body weight may be administered once every two weeks as a single IV or SC injection.

Patients on dialysis –The recommended starting dose of 0,6 µg/kg body weight, may be administered once every two weeks as a single IV or SC injection in order to increase the haemoglobin to greater than 11 g/dℓ (6,83 mmol/L).

The dose of Mircera may be increased by approximately 25 % to 50 % of the previous dose if the rate of rise in haemoglobin is less than 1,0 g/dℓ (0,621 mmol/L) over a month. Further increases of approximately 25 % to 50 % may be made at monthly intervals until the individual target haemoglobin level is obtained.

If the rate of rise in haemoglobin is greater than 2 g/dℓ (1,24 mmol/L) in one month or if the haemoglobin levels exceed 12 g/dℓ, reduce the dose of Mircera by 25 % to 50 % .

If the haemoglobin level exceeds 13 g/dℓ 8,07 mmol/L), therapy is to be interrupted until the haemoglobin level falls below 13 g/dℓ, and then restarted with approximately 50 % of the previously administered dose. After dose interruption, a haemoglobin decrease of approximately 0,35 g/dℓ per week is expected.

Patients treated once every two weeks whose haemoglobin concentration is in the target range may receive Mircera administered once monthly using the dose equal to twice the previous once every two weeks dose.

Dose adjustments should not be made more often than once a month.

Patients currently treated with an epoetin.

Patients currently treated can be converted to Mircera administered once a month or, if desired, once every 2 weeks as a single IV or SC injection. The starting dose of Mircera is based on the calculated previously given weekly dose of darbepoetin alfa or epoetin at the time of substitution as described in the table below**.** The first injection of Mircera should be administered at the next scheduled dose of the previously administered darbepoetin alfa or epoetin.

Previous Weekly Epoetin Dose (Units/week)	**Previous Weekly Darpoetin Alfa Dose (µg/week)**	**Mircera Dose**	
		Once Monthly (µg/month)	**Once Every Two Weeks (µg/q2w)**
< 8 000	< 40	120	60
8 000 -16 000	40 – 80	200	100
> 16 000	> 80	360	180

If a dose adjustment is required to maintain the target haemoglobin concentration above 10 g/dℓ, the monthly dose may be adjusted by approximately 25 %.

If the rate of rise in haemoglobin is greater than 2 g/dℓ (1,24 mmol/L) over a month or if the haemoglobin levels exceed 12 g/dℓ (7,45 mmol/L), the dose is to be reduced by approximately 25 to 50 %.

If the haemoglobin level exceeds 13 g/dℓ (8,07 mmol/L, therapy is to be interrupted until the haemoglobin level falls below 13 g/dℓ and then restarted with approximately 50 % of the previously

administered dose. After dose interruption a haemoglobin decrease of approximately 0,35 g/dℓ (0,22 mmol/L) per week is expected.

Dose adjustments should not be made more often than once a month.

Since the treatment experience is limited in patients on peritoneal dialysis, regular Hb monitoring and strict adherence to dose adjustment guidance are recommended in these patients.

Treatment interruption: Treatment with Mircera is usually long-term. However, it can be interrupted at any time, if necessary.

Missed dose: If one dose of Mircera is missed, the missed dose should be administered as soon as possible and administration of Mircera is to be restarted at the prescribed dosing frequency.

Special dosage instructions

Paediatric use: No dose recommendations can be made for use in patients aged less than 18 years due to the limited data on safety and efficacy.

Geriatric use: Of the 1 789 Mircera -treated CKD patients in Phase II and Phase III clinical studies of Mircera, 24 % were 65 to 74 years, while 20 % were 75 years and over. Based on population analyses, no adjustment of the starting dose is required in patients aged 65 years or older.

Hepatic impairment: No adjustments of the starting dose nor dose modification rules are required in patients with any degree of hepatic impairment.

4.3 Contraindications

Mircera is contraindicated in patients with:

- Uncontrolled hypertension.
- Known hypersensitivity to the active substance or any of the excipients listed in section 6.1.
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

WARNINGS AND SPECIAL PRECAUTIONS

The safety and efficacy of Mircera therapy in other indications than in anaemia associated with CKD, including anaemia in patients with cancer, has not been established.

Supplementary iron therapy: In order to ensure effective erythropoiesis, iron status should be evaluated for all patients prior to and during treatment and supplementary iron therapy may be necessary and conducted in accordance with treatment guidelines.

Pure Red Cell Aplasia (PRCA): caused by anti-erythropoietin antibodies has been reported in association with Mircera. These antibodies have been shown to cross-react with all ESAs, and patients suspected or confirmed to have antibodies to erythropoietin should not be switched to Mircera.

PRCA in patients with Hepatitis C: A paradoxical decrease in haemoglobin and development of severe anaemia associated with low reticulocyte counts should prompt discontinuation of treatment with Mircera and testing for anti-erythropoietin antibodies. Cases have been reported in patients with hepatitis C treated with interferon and ribavirin, when erythropoietins, such as Mircera were used concomitantly. Mircera is not approved in the management of anaemia associated with hepatitis C.

Blood pressure monitoring: Blood pressure may rise during treatment of anaemia with Mircera. Blood pressure should be adequately controlled before, at initiation of, and during treatment with Mircera. If high blood pressure is difficult to control by medical treatment or dietary measures, the dose of Mircera must be reduced or withheld (see section 4.2).

Haemoglobin concentration: In patients with chronic kidney disease, maintenance haemoglobin concentration should not exceed the upper limit of the target haemoglobin concentration

recommended in section 4. In clinical trials, an increased risk of death, serious cardiovascular events including thrombosis or cerebrovascular events including stroke, was observed when ESAs such as Mircera were administered to target a haemoglobin of greater than 12 g/dℓ (7,5 mmol/L). Controlled clinical trials have not shown significant benefits attributable to the administration of epoetins when haemoglobin concentration is increased beyond the level necessary to control symptoms of anaemia and to avoid blood transfusion.

Effect on tumour growth: Mircera, is a growth factor that primarily stimulates red blood cell production. Erythropoietin receptors may be expressed on the surface of a variety of tumour cells. There is a concern that ESA's could stimulate the growth of any type of malignancy. Two controlled clinical studies in which epoetins were administered to patients with various cancers including head and neck cancers, and breast cancer, have shown an unexplained excess mortality.

The safety and efficacy of Mircera therapy has not been established in patients with haemoglobinopathies, seizures, bleeding or a recent history of bleeding requiring transfusions or with a platelet level greater than 500 x 109/ℓ. Therefore, caution should be used in these patients.
Mircera is not recommended for use in patients aged less than 18 years due to lack of data on safety and efficacy.
In order to improve traceability of biological medicinal products, the tradename of the administered product should be clearly recorded (or stated) in the patient file.
Mircera contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially sodium free.

Sugar alcohol: Mircera contains mannitol and may have a laxative effect.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed. The clinical results do not indicate any interaction of Mircera with other medicinal products. The effect of other medicines on the pharmacokinetics and pharmacodynamics of Mircera was explored using a population analysis approach. There was no

indication of an effect of concomitant medications on the pharmacokinetics and pharmacodynamics of Mircera.

4.6 Fertility, pregnancy and lactation

Pregnancy

As safety in pregnancy and lactation has not been established, Mircera is contraindicated during pregnancy (see section 4.3). There are no adequate data on the use of Mircera in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Breastfeeding mothers

It is unknown whether Mircera is excreted in human breast milk.

In animals Mircera is excreted into maternal milk. Mothers receiving Mircera should not breastfeed their infants.

4.7 Effects on ability to drive and use machines

No studies on the ability to drive and use machines have been performed. However, no effects are expected based on the mechanism of action and the known safety profile of Mircera.

Drug Abuse and Dependence: Misuse by non-anaemic persons may lead to an excessive increase in Hb. This may be associated with life threatening complications of the cardiovascular system.

UNDESIRABLE SIDE EFFECTS

Clinical Trials

The safety database for Mircera from controlled clinical trials comprised 1 939 chronic kidney disease (CKD) patients treated with Mircera.

The most frequent reported adverse reaction was hypertension (common).

The frequencies are defined as follows:

Very common (≥ 1/10); common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000) and very rare (< 1/10 000).

Adverse reactions attributed to the treatment with Mircera in controlled clinical trials in CKD patients.

System organ class	Frequency	Adverse reaction
Immune system disorders	Rare	Hypersensitivity
Nervous system disorders	Uncommon	Headache
	Rare	Hypertensive encephalopathy
Vascular disorders	Common	Hypertension
	Rare	Hot flushes
Skin and subcutaneous tissue disorders	Rare	Maculo-papular rash
Injury, poisoning and procedural complications	Uncommon	Vascular access thrombosis

All other events attributed to Mircera were reported with rare frequency and the majority was mild to moderate in severity. These events were consistent with co-morbidities known in the population.

Data from a controlled clinical trial with epoetin alfa reported an incidence of stroke as common.

Laboratory Abnormalities

During treatment with Mircera, a slight decrease in platelet counts, remaining within the normal range, was observed in clinical studies.

Platelet counts below 100 x 10^9/ℓ were observed in 7 % of patients treated with Mircera and 4 % of patients treated with ESAs.

Supplementary iron therapy is recommended for all patients with serum ferritin values below 100 µg/ℓ or whose transferrin saturation is below 20 %. To ensure effective erythropoiesis, iron status should be evaluated for all patients prior to and during treatment.

Failure to respond to Mircera therapy should prompt a search for causative factors: Deficiencies of iron, folic acid or vitamin B12 reduce the effectiveness of ESAs and should therefore be corrected. Intercurrent infections, inflammatory or traumatic episodes, occult blood loss, haemolysis, severe aluminium toxicity, underlying haematologic diseases, or bone marrow fibrosis may also compromise the erythropoietic response. A reticulocyte count should be considered as part of the evaluation.

If all the conditions mentioned are excluded and the patient has a sudden drop of haemoglobin associated with reticulocytopenia and anti-erythropoietin antibodies, examination of the bone marrow for the diagnosis of Pure Red Cell Aplasia (PRCA) should be considered. If PRCA is diagnosed, therapy with Mircera must be discontinued and patients should not be switched to another ESA.

Post-marketing

Neutralising anti-erythropoietin antibody-mediated pure red cell aplasia (AEAB-PRCA) has been reported. When PRCA is diagnosed, therapy with Mircera must be discontinued, and patients should not be switched to another erythropoietic agent (see WARNINGS AND SPECIAL PRECAUTIONS).

Adverse reactions observed during post-marketing:

System organ class	Adverse reaction
Blood and lymphatic system disorders	Thrombocytopenia
	Pure red cell aplasia
Immune system disorders	Anaphylactic reaction
Vascular disorders	Thrombosis, Pulmonary embolism
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome/ toxic epidermal necrolysis

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

4.9 Overdose

Overdose can result in manifestations of an exaggerated pharmacodynamic effect, e.g. excessive erythropoiesis which may lead to arterial and venous thromboembolism, including stroke, myocardial infarction and shunt thrombosis.

In case of excessive haemoglobin levels, Mircera should be temporarily with held (see section 4.2). If clinically indicated, phlebotomy may be performed.

5 Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antianemic preparations, ATC code: B03XA03

Mechanism of Action

Methoxy polyethylene glycol-epoetin beta is epoetin beta complexed with methoxy polyethylene glycol (PEG) and is a chemically synthesised sustained erythropoietin receptor activator or erythropoietin stimulating agent (ESA).

It has a molecular weight of approximately 60 000 daltons for methoxy polyethylene glycol-epoetin beta with the PEG-moiety having an approximate molecular weight of 30 000 daltons.

The active component, epoetin beta, stimulates erythropoiesis by interaction with the erythropoietin receptor on progenitor cells in the bone marrow. As primary growth factor for erythroid development, the natural hormone erythropoietin is produced in the kidney and released into the bloodstream in response to hypoxia. In responding to hypoxia, the natural hormone erythropoietin interacts with erythroid progenitor cells to increase red cell production.

5.2 Pharmacokinetic properties

The pharmacokinetics of the molecule methoxy polyethylene glycol-epoetin beta were studied in healthy volunteers and in anaemic patients with chronic kidney disease (CKD) including patients on dialysis and not on dialysis.

In CKD patients, clearance and volume of distribution of methoxy polyethylene glycol-epoetin beta were not dose dependent.

In CKD patients, the pharmacokinetics of methoxy polyethylene glycol-epoetin beta were studied after the first dose and after administrations on week 9 and on week 19 or 21. Multiple dosing had no effect on clearance, volume of distribution and bioavailability of methoxy polyethylene glycol-epoetin beta. After administration every 4 weeks in CKD patients, there was no meaningful accumulation of methoxy polyethylene glycol-epoetin beta, as demonstrated by a ratio of accumulation of 1,03. After administration every 2 weeks, the ratio of accumulation was 1,12.

A comparison of serum concentrations of methoxy polyethylene glycol-epoetin beta measured before and after haemodialysis in 41 CKD patients showed that haemodialysis has no effect on the pharmacokinetics of methoxy polyethylene glycol-epoetin beta.

An analysis in 126 CKD patients showed no pharmacokinetic difference between patients on dialysis and patients not on dialysis.

The results of a study in 42 healthy volunteers indicated that the site of subcutaneous injection (abdomen, arm or thigh) has no clinically relevant effect on the pharmacokinetics, pharmacodynamics or local tolerability of methoxy polyethylene glycol-epoetin beta. Based on these results, all three sites are considered suitable for subcutaneous injection with methoxy polyethylene glycol-epoetin beta.

Absorption

Absorption after subcutaneous administration

Following SC administration to CKD patients, the maximum serum concentrations of methoxy polyethylene glycol-epoetin beta were observed 72 hours (median value) after administration in patients on dialysis and 95 hours (median value) after administration in patients not on dialysis.

The absolute bioavailability of methoxy polyethylene glycol-epoetin beta after SC administration was 62 % and 54 %, in dialysis patients and patients not on dialysis, respectively.

Distribution

A study in 400 CKD patients showed that the volume of distribution of methoxy polyethylene glycol-epoetin beta is approximately 5 ℓ.

Elimination

Following IV administration to CKD patients, the $t_{1/2}$ for methoxy polyethylene glycol-epoetin beta was 134 hours, and the total systemic clearance was 0,494 mℓ/h per kg. Following SC

administration the observed terminal elimination half-life was 142 hours in CKD patients not on dialysis and 139 hours in CKD patients on dialysis.

Pharmacokinetics in Special Populations

Hepatic impairment

The pharmacokinetics of methoxy polyethylene glycol-epoetin beta after a single dose are similar in patients with severe hepatic impairment as compared to healthy subjects.

Paediatric Patients

A phase II, dose-finding, open-label, multiple dose, multicenter study was conducted in 64 paediatric patients (aged 5 - 17 years old) with CKD who were on haemodialysis, to determine the effective starting dose of methoxy polyethylene glycol-epoetin beta IV when switching from maintenance treatment with another ESA (epoetin alfa/beta or darbepoetin alfa). The primary efficacy endpoint in this study (change in Hb concentration (g/dℓ) between the baseline and evaluation periods) has been met. Overall, the adverse event profile observed was consistent with the safety profile in adults.

Other special populations

Population analyses evaluated the potential effects of demographic characteristics on the pharmacokinetics of methoxy polyethylene glycol-epoetin beta. Results of these analyses showed that no adjustments of the starting dose are necessary for age (> 18 years), gender, or race. A population pharmacokinetic analysis also showed no pharmacokinetic differences between patients on dialysis and patients not on dialysis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate monohydrate

Sodium sulphate

Mannitol (E421)

Methionine

Poloxamer 188

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in the refrigerator at 2 °C to 8 °C.

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

Do not freeze. Do not shake the pre-filled syringe.

The end-user may remove the product from refrigeration for storage at room temperature (not above 30 °C) for one single period of 1 month. Once removed from the refrigerator the product must be used within this period.

Store all medicines out of reach of children.

6.5 Nature and contents of container

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.

Not all product strengths may be marketed.

6.6 Special precautions for disposal and other handling

The pre-filled syringe is ready for use. The sterile pre-filled syringe does not contain any preservative and is to be used for a single injection only. Only one dose should be administered per syringe. Only solutions which are clear, colourless to slightly yellowish and free of visible particles must be injected.

Do not shake.

Allow the pre-filled syringe to reach room temperature before injecting.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

DATE OF REVISION OF THE TEXT

Last revision: 07 December 2022

Botswana	S2 BOT1202166/7/8/9
Namibia	NS2 10/30.4/0088/9/90/12/3
Zimbabwe	PP 2014/10.1/4835/6/7

Approved Manufacturer(s):

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