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Mircera *(methoxy polyethylene glycol-epoetin beta)*

An overview of Mircera and why it is authorised in the EU

What is Mircera and what is it used for?

Mircera is a medicine used to treat the symptoms of anaemia (low levels of red blood cells) in adults and children aged 3 months and older with chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly).

In children, Mircera is intended for patients who have stable levels of haemoglobin (the protein in red blood cells that carries oxygen around the body) when changing from another erythropoiesis stimulating agent (ESA), a medicine that stimulates the bone marrow to make more red blood cells.

Mircera contains the active substance methoxy polyethylene glycol-epoetin beta.

How is Mircera used?

Treatment with Mircera should be started under the supervision of a doctor who has experience in the management of patients with kidney disease.

Mircera is given as an injection under the skin or into a vein. The dose and the frequency of dosing depend on whether or not Mircera is replacing another medicine used to stimulate the production of red blood cells. Doses should be adjusted according to the patient's response.

Mircera is intended for long-term use. Adult patients can inject themselves once they have been trained appropriately. Mircera should be given to children by a healthcare professional or by an adult caregiver who has been appropriately trained.

The medicine can only be obtained with a prescription. For more information about using Mircera, see the package leaflet or contact your doctor or pharmacist.

How does Mircera work?

Patients with chronic kidney disease may not produce enough erythropoietin, a hormone that stimulates the production of red blood cells. The active substance in Mircera, methoxy polyethylene glycol-epoetin beta, works like natural erythropoietin to stimulate red blood cell production, because it can attach itself to the same receptors (targets) as erythropoietin. However, the way it interacts with the receptor is slightly different from natural erythropoietin, which gives it a longer effect. It is also cleared from the body less quickly. As a result, Mircera can be given less often than natural erythropoietin.

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The active substance in Mircera is made up of epoetin beta attached to a chemical called methoxy-polyethylene glycol.

What benefits of Mircera have been shown in studies?

Adults

Mircera was shown to be as effective as the comparator medicines in correcting and maintaining haemoglobin levels in six main studies involving a total of 2,399 adults with anaemia associated with chronic kidney disease. Mircera was compared with other medicines used to stimulate red blood cell production. In all six studies, the main measure of effectiveness was the change in haemoglobin levels. Most patients also received iron to prevent deficiency (low iron levels) during the studies.

Two of these studies involved patients who were starting treatment for anaemia. The first study, in 181 patients on dialysis (a blood clearance technique used in advanced kidney disease), looked at Mircera injected into a vein every two weeks over 24 weeks and compared it with epoetin alfa or beta. The second study, in 324 patients not on dialysis, looked at Mircera injected under the skin every two weeks over 28 weeks, comparing it with darbepoetin alfa.

In these studies, 126 (93%) of the 135 patients on dialysis, and 158 (98%) of the 162 not on dialysis had a significant increase in haemoglobin levels with Mircera. Similar response rates were seen in the patients taking the comparator medicines. The second study showed that patients taking Mircera and those taking darbepoetin alfa had similar increases in haemoglobin levels (around 2 g/dl).

The other four studies (in 1,894 patients) were carried out in patients on dialysis who had already been receiving medicines to stimulate red blood cell production. In these studies, patients either remained on the medicines they were already receiving or changed to Mircera, injected into a vein or under the skin every two or four weeks. The effectiveness of the two treatment options was compared over 36 weeks. These studies showed that patients who changed to Mircera maintained their haemoglobin levels as effectively as the patients who remained on their existing medicines. There was no overall change in haemoglobin levels over the course of these studies with any of the treatments.

Children

Two studies have shown that Mircera is effective in maintaining haemoglobin levels within a recommended range of 10 to 12 grams per decilitre (g/dL) in children, after switching from another ESA. Neither study compared Mircera with placebo (a dummy treatment) or other medicines.

The first study involved 64 children, aged between 5 and 17 years, with anaemia due to chronic kidney disease, who were undergoing haemodialysis (a procedure for removing waste products from the blood) and who had switched from another ESA. Mircera was given as an injection into a vein every 4 weeks. After 20 weeks of treatment, haemoglobin levels decreased on average by 0.1 g/dL; 81% of patients maintained haemoglobin levels within the range of 10 to 12 g/dL, and in 75% haemoglobin levels did not increase or decrease by more than 1g/dL.

The second study involved 40 children aged from 3 months to 17 years, with anaemia due to chronic kidney disease and stable haemoglobin levels, who had switched from another ESA. Mircera was given as an injection under the skin every 4 weeks. After 20 weeks of treatment, haemoglobin levels increased on average by 0.5g/dL; 63% of patients maintained haemoglobin levels within the range of 10 to 12 g/dL, and in 50% haemoglobin levels did not increase or decrease by more than 1g/dL.

What are the risks associated with Mircera?

For the full list of side effects and restrictions with Mircera, see the package leaflet.

The most common side effect with Mircera (which may affect between 1 and 10 patients in 100) is hypertension (high blood pressure). Mircera must not be used in patients who have high blood pressure that is not controlled.

Why has Mircera been approved?

The European Medicines Agency concluded that Mircera corrected and maintained haemoglobin levels in patients with chronic kidney disease and that its effects are comparable with those of other ESAs. The Agency considered that Mircera's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

Mircera has been shown to maintain appropriate levels of haemoglobin in children with anaemia due to chronic kidney disease whose disease is stable following use of another ESA. Although safety data in children are limited, the safety profile in children is similar to that observed for adults and therefore considered manageable.

Other information about Mircera

Mircera received a marketing authorisation valid throughout the European Union on 20 July 2007.

Further information on Mircera can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/mircera

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