EMA/CHMP/227862/2012
EMEA/H/C/000739

EPAR summary for the public

Mircera

methoxy polyethylene glycol-epoetin beta

This document is a summary of the European public assessment report (EPAR) for Mircera. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Mircera.

What is Mircera?

Mircera is a solution for injection that contains the active substance methoxy polyethylene glycol-epoetin beta. It is available in vials and in pre-filled syringes at various strengths ranging from 50 to 1,000 micrograms per millilitre.

What is Mircera used for?

Mircera is used to treat anaemia (low red blood cell counts) that is causing symptoms in adults with chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly).

The medicine can only be obtained with a prescription.

How is Mircera used?

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

Mircera can be injected 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. See the summary of product characteristics (also part of the EPAR) for full details. Doses should be adjusted according to the patient's response, to obtain haemoglobin levels within the recommended range (between 10 and 12 grams per decilitre). Haemoglobin is the protein in red blood cells that carries oxygen around the body. Haemoglobin levels should be monitored every two weeks until they

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

are stable, and then periodically. The lowest dose that provides adequate control of symptoms should be used.

Mircera is intended for long-term use. Patients can inject themselves once they have been trained appropriately.

How does Mircera work?

A hormone called erythropoietin stimulates the production of red blood cells from the bone marrow. Erythropoietin is produced by the kidneys. In patients with chronic kidney disease, the main cause of their anaemia is a lack of natural erythropoietin. 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 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.

The active substance in Mircera is made up of epoetin beta attached to a chemical called methoxy-polyethylene glycol. The epoetin beta is produced by 'recombinant DNA technology': it is made by a cell that has received a gene, which makes it able to produce epoetin beta.

How has Mircera been studied?

Mircera has been studied 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. 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.

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.

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.

What benefit has Mircera shown during the studies?

Mircera was as effective as the comparator medicines in correcting and maintaining haemoglobin levels. In the studies of patients starting treatment for anaemia for the first time, 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).

In the studies of patients who had already been receiving medicines to stimulate red blood cell production, 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.

What is the risk associated with Mircera?

The most common side effect with Mircera (seen in between 1 and 10 patients in 100) is hypertension (high blood pressure). For the full list of all side effects reported with Mircera, see the package leaflet.

Mircera must not be used in people who are hypersensitive (allergic) to methoxy polyethylene glycol-epoetin beta or any of the other ingredients. It must also not be used in patients who have high blood pressure that is not controlled.

Why has Mircera been approved?

The CHMP concluded that Mircera corrected and maintained haemoglobin levels in patients with chronic kidney disease and that its effects are comparable with those of other epoetins. The Committee decided that Mircera's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Mircera:

The European Commission granted a marketing authorisation valid throughout the European Union for Mircera on 20 July 2007.

The full EPAR for Mircera can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Mircera, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2012.