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EPAR summary for the public

Aranesp

darbepoetin alfa

This is a summary of the European public assessment report (EPAR) for Aranesp. 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 Aranesp.

What is Aranesp?

Aranesp is a solution for injection in a vial, a pre-filled syringe or a pre-filled pen. It contains the active substance darbepoetin alfa. Aranesp exists in various strengths, from 25 to 500 micrograms per millilitre.

What is Aranesp used for?

Aranesp is used to treat anaemia (low red blood cell counts) that is causing symptoms. It is used in two groups of patients:

- adults and children with 'chronic renal failure' (long-term, progressive decrease in the ability of the kidneys to work properly);
- adults who are receiving chemotherapy for 'non-myeloid' cancer (cancer not originating in the bone marrow).

The medicine can only be obtained with a prescription.

How is Aranesp used?

Aranesp treatment should be initiated by a doctor who has experience in treating the types of anaemia mentioned above.

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
An agency of the European Union

For patients with chronic renal failure, Aranesp can be injected into a vein or under the skin. It must be injected under the skin in patients receiving chemotherapy. The dose and frequency of injection depend on why Aranesp is being used, and are to be adjusted, according to the patient's response, to obtain haemoglobin levels that remain 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. The lowest dose that provides adequate control of symptoms should be used.

Aranesp can be injected by the patient or their carer if they have been trained appropriately. For full details, see the package leaflet.

How does Aranesp 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 renal failure, anaemia can be caused by a lack of erythropoietin. In patients receiving chemotherapy, anaemia can be caused by the body not responding sufficiently to the erythropoietin it has naturally.

Darbepoetin alfa, the active substance in Aranesp, acts exactly like the natural erythropoietin made by the body to stimulate red blood cell production, but it is very slightly different in its structure. This means that darbepoetin alfa has a longer duration of action, and can be given less often than natural erythropoietin. The darbepoetin alfa in Aranesp is produced by a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced, which make the cells able to produce darbepoetin alfa.

How has Aranesp been studied?

Aranesp has been studied in patients with chronic renal failure in four studies involving over 1,200 patients, in which it was compared with recombinant human erythropoietin. The main measure of effectiveness was the increase in haemoglobin. Aranesp has also been studied in 124 children with chronic renal failure to check that it is absorbed in the same way as in adults.

Aranesp has also been compared with placebo (a dummy treatment) in two studies involving 669 patients receiving chemotherapy for cancer such as lung cancer, myeloma or lymphoma. The main measure of effectiveness was the reduction in number of patients who needed a blood transfusion.

What benefit has Aranesp shown during the studies?

Aranesp was as effective as human recombinant erythropoietin at increasing the haemoglobin levels in patients with chronic renal failure, and at keeping these levels maintained after they had been improved, whether given as an injection into a vein or under the skin.

In cancer patients receiving chemotherapy, fewer of the patients treated with Aranesp needed a blood transfusion than those given placebo.

What is the risk associated with Aranesp?

In kidney failure patients, the most common side effects with Aranesp (seen in more than 1 patient in 10) are hypersensitivity (allergy) and hypertension (high blood pressure) while in cancer patients the most common are hypersensitivity and oedema (fluid retention). For the full list of all side effects reported with Aranesp, see the package leaflet.

Aranesp must not be used in people who are hypersensitive (allergic) to darbepoetin alfa or any of the other ingredients. It must not be used in patients who have poorly controlled high blood pressure.

Why has Aranesp been approved?

The CHMP decided that Aranesp's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Aranesp

The European Commission granted a marketing authorisation valid throughout the European Union for Aranesp on 8 June 2001.

The full EPAR for Aranesp 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 Aranesp, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2013.