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Aranesp (*darbepoetin alfa*)

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

What is Aranesp and what it is used for?

Aranesp is a medicine 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, decreasing 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).

Aranesp contains the active substance darbepoetin alfa.

How is Aranesp used?

Aranesp can only be obtained with a prescription and treatment should be started by a doctor who has experience in treating the types of anaemia mentioned above.

Aranesp is available in a vial, a pre-filled syringe or a pre-filled pen. It is provided in various strengths.

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 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. For more information about using Aranesp, see the package leaflet or contact your doctor or pharmacist.

How does Aranesp work?

In patients receiving chemotherapy or with kidney problems, anaemia can be caused by a lack of a hormone called erythropoietin, or by the body not responding well enough to erythropoietin. The active substance in Aranesp, darbepoetin alfa works in exactly the same way as the natural hormone to stimulate the production of red blood cells in the bone marrow. It is very slightly different in its

structure to the natural hormone. Because of the slight changes to the structure, darbepoetin alfa remains in the body for longer than natural erythropoietin.

What benefits of Aranesp have been shown in studies?

Aranesp has been shown to be effective in the treatment of chronic renal failure in four studies involving over 1,200 patients. Aranesp was as effective as human recombinant erythropoietin at increasing the haemoglobin levels and at keeping these levels maintained, whether given as an injection into a vein or under the skin.

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.

In two studies involving 669 patients receiving chemotherapy, Aranesp was more effective than placebo (a dummy treatment) and fewer patients needed a blood transfusion.

What are the risks associated with Aranesp?

In kidney failure patients, the most common side effects with Aranesp (which may affect more than 1 in 10 people) are hypersensitivity (allergy) and hypertension (high blood pressure) while in cancer patients the most common are hypersensitivity and oedema (fluid retention).

Aranesp must not be used in patients who have poorly controlled high blood pressure. For the full list of side effects and restrictions, see the package leaflet

Why is Aranesp authorised in the EU?

The European Medicines Agency decided that Aranesp's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Aranesp?

The company that markets Aranesp will provide educational packs for patients and healthcare professionals including information on how to self-inject the medicine, a training checklist and a demonstration device.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Aranesp have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Aranesp are continuously monitored. Side effects reported with Aranesp are carefully evaluated and any necessary action taken to protect patients.

Other information about Aranesp

Aranesp received a marketing authorisation valid throughout the EU on 8 June 2001.

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

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