European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NESPO

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Nespo?

Nespo is a solution for injection in a vial, a pre-filled syringe or a pre-filled pen. It contains the active substance darbepoetin alfa. Nespo exists in various strengths, from 10 to 500 micrograms per millilitre. See the Package Leaflet for full details.

What is Nespo used for?

Nespo is used to treat anaemia (fewer red blood cells in the blood than normal) in two groups of patients:

- adults and children over one year of age with anaemia caused by long-term kidney failure, when the body does not produce enough of the natural hormone erythropoietin,
- adult patients with certain types of cancer who are receiving chemotherapy (the medicines used to treat cancer), when the chemotherapy stops the bone marrow producing enough blood cells. The types of cancer where Nespo can be used are 'non-myeloid' (do not affect the bone marrow).

The medicine can only be obtained with a prescription.

How is Nespo used?

Nespo treatment should be initiated by a doctor who has experience in treating either of the two types of anaemia mentioned above. Nespo is injected intravenously (into a vein) or subcutaneously (under the skin). The dose used depends on why Nespo is used, varying from 0.45 micrograms per kilogram every week (or 0.75 micrograms/kg every other week) in adults and children with kidney failure aged 11 years or older, to 6.75 micrograms/kg every three weeks in cancer patients. Lower doses may be necessary for children with kidney failure aged 10 years or below. In all cases the doses are adjusted to obtain haemoglobin levels that remain within the recommended range. Haemoglobin is the protein in red blood cells that carries oxygen around the body.
Doses and dose frequency (how often Nespo is given) are adjusted depending on the response. Nespo is supplied ready for use in a pre-filled syringe or pre-filled pen, which can be used by the patient or their carer. See the Package Leaflet for full instructions for use.

How does Nespo work?

A hormone called erythropoietin stimulates the production of red blood cells from the bone marrow. Darbepoetin alfa, the active substance in Nespo, acts exactly like the natural erythropoietin made by the body, but it is very slight different in its structure, and this means that darbepoetin alfa has a longer duration of action, and can be given less often than natural erythropoietin. Darbepoetin alfa is

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes the cell able to produce darbepoetin alfa. In patients with long-term kidney failure, the main cause of their anaemia is a lack of natural erythropoietin. A lack of natural erythropoietin is also one of the causes of anaemia in patients receiving chemotherapy. Nespo works by stimulating the production of red blood cells in the same way as natural erythropoietin.

How has Nespo been studied?
The effectiveness of Nespo has been studied in patients with long-term kidney disease, where it was compared with recombinant human erythropoietin in four studies involving over 1,200 patients, and in patients receiving chemotherapy for cancer such as lung cancer, myeloma or lymphoma, where it was compared with placebo (a dummy treatment) in two studies involving 669 patients. The main measure of effectiveness in patients with kidney disease was the increase in haemoglobin. In patients receiving chemotherapy, the main measure of effectiveness was the reduction in number of patients who needed a blood transfusion.
Nespo has also been studied in 124 children with long-term kidney disease to check that it is absorbed in the same way as in adults.

What benefit has Nespo shown during the studies?
Nespo was as effective as human recombinant erythropoietin at increasing the haemoglobin levels in patients with kidney disease, and at keeping these levels maintained after they had been improved, whether given as an intravenous or subcutaneous injection. In cancer patients receiving chemotherapy, fewer patients treated with Nespo needed a blood transfusion compared with those given placebo.

What is the risk associated with Nespo?
The most common side effects with Nespo (seen in between 1 and 10 patients in 100) are headache, hypertension (high blood pressure), thrombosis (blood clots), injection site pain, arthralgia (joint pain) and peripheral oedema (fluid retention). For the full list of all side effects reported with Nespo, see the Package Leaflet.
Nespo should not be used in people who may be hypersensitive (allergic) to darbepoetin alfa or any of the other ingredients, or in patients who have poorly controlled high blood pressure.

Why has Nespo been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Nespo's benefits are greater than its risks for the treatment of anaemia associated with chronic renal failure in adults and paediatric patients, and of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The Committee recommended that Nespo be given marketing authorisation.

Other information about Nespo:
The European Commission granted a marketing authorisation valid throughout the European Union for Nespo to Dompé Biotec S.p.A. on 8 June 2001. The marketing authorisation was renewed on 8 June 2006.

The full EPAR for Nespo is available here.

This summary was last updated in 09-2007.