EMA/683554/2015
EMEA/H/C/000116

EPAR summary for the public

NeoRecormon

epoetin beta

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

What is NeoRecormon?

NeoRecormon is a medicine that stimulates red-blood-cell growth. It is available as a powder and solvent in a multidose vial, to be made up into a solution for injection. It is also available as a pre-filled syringe. NeoRecormon is available in various strengths from 500 to 50,000 international units (IU). It contains the active substance epoetin beta.

What is NeoRecormon used for?

NeoRecormon is used in the following situations:

- to treat anaemia (low red blood cell counts) that is causing symptoms in adults and children with chronic renal failure (long-term, progressive decrease in the ability of the kidneys to work properly);
- to prevent anaemia in premature babies;
- to treat anaemia that is causing symptoms in adults who are receiving chemotherapy for 'non-myeloid' cancer (cancer that does not affect the bone marrow);
- to increase the amount of blood that can be taken from adult patients with moderate anaemia who are going to have an operation and need to have a supply of their own blood before surgery (autologous blood transfusion).This is only done when blood storage procedures are not available or are insufficient because the surgery requires a large volume of blood.

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How is NeoRecormon used?

Treatment with NeoRecormon should be initiated by a doctor who has experience in the care of patients with the types of anaemia that NeoRecormon is used to treat and prevent. The medicine can only be obtained with a prescription.

For patients with chronic renal failure, NeoRecormon can be injected into a vein or under the skin, but it must be injected under the skin in premature babies and patients receiving chemotherapy, and into a vein in patients who are going to have their blood extracted for their surgery. The dose, the frequency of injection, and how long it is used for depend on why NeoRecormon is used, and are adjusted according to the patient's response to treatment. For more details, see the package leaflet.

How does NeoRecormon work?

The active substance in NeoRecormon, epoetin beta, is a copy of a human hormone called erythropoietin. Erythropoietin is produced by the kidneys and stimulates the production of red blood cells from the bone marrow. In patients receiving chemotherapy or with chronic renal failure, anaemia can be caused by a lack of erythropoietin, or by the body not responding enough to the erythropoietin it has naturally. The epoetin beta in NeoRecormon works in the body in the same way as the natural hormone to stimulate red blood cell production.

How has NeoRecormon been studied?

The effectiveness of NeoRecormon to treat or prevent anaemia has been studied in many studies including anaemia in chronic renal failure (1,663 patients, including some comparative studies against placebo (a dummy treatment)), autologous blood transfusion (419 patients, comparison with placebo), anaemia in premature babies (177 babies, comparison with no treatment), and in cancer patients (1,204 patients with different types of cancer, comparison with placebo). The main measures of effectiveness in most of the studies were whether NeoRecormon increased haemoglobin levels or whether it reduced the need for blood transfusions.

What benefit has NeoRecormon shown during the studies?

NeoRecormon was more effective than placebo at increasing haemoglobin levels in patients with various types of anaemia, including those with chronic renal failure. It also increased the amount of blood that could be taken from patients before surgery for autologous blood transfusion and reduced the need for transfusion in premature babies and in cancer patients receiving chemotherapy.

What is the risk associated with NeoRecormon?

The types of side effects seen with NeoRecormon depend on the cause of the patient's anaemia. The most common side effects (seen in between 1 and 10 patients in 100) are hypertension (high blood pressure), headache and thromboembolic events (formation of blood clots in the blood vessels). For the full list of all side effects reported with NeoRecormon, see the package leaflet.

NeoRecormon must not be used in patients who have poorly controlled high blood pressure. In patients who are to undergo autologous blood transfusion, NeoRecormon must not be used if they have had a heart attack or stroke within the last month, if they have angina pectoris (a severe type of chest pain), or if they are at risk of deep venous thrombosis (DVT, formation of blood clots in the deep veins of the body, usually in the leg). The multidose formulation of NeoRecormon contains benzyl alcohol and must

not be given to children below three years of age. For the full list of restrictions, see the package leaflet.

Why has NeoRecormon been approved?

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

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

A risk management plan has been developed to ensure that NeoRecormon is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for NeoRecormon, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about NeoRecormon

The European Commission granted a marketing authorisation valid throughout the European Union for NeoRecormon on 17 July 1997.

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

This summary was last updated in 11-2015.