EMEA/H/C/000116

NeoRecormon (*epoetin beta*)

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

What is NeoRecormon and what is it used for?

NeoRecormon is a medicine that stimulates red-blood-cell growth. It 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.

NewRecormon contains the active substance epoetin beta.

How is NeoRecormon used?

Treatment with NeoRecormon should be started 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.

NeoRecormon is available as a pre-filled syringe in various strengths, from 500 to 30,000 international units (IU). The dose, the frequency and mode of injection (into a vein or under the skin), and how long it is used for depend on why NeoRecormon is used, and are adjusted according to the patient's response to treatment.

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

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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.

What benefits of NeoRecormon have been shown in studies?

The effectiveness of NeoRecormon to treat or prevent anaemia has been investigated 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.

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 are the risks associated with NeoRecormon?

For the full list of side effects and restrictions with NeoRecormon, see the package leaflet.

The types of side effects seen with NeoRecormon depend on the cause of the patient's anaemia. The most common side effects (which may affect up to 1 in 10 people) include hypertension (high blood pressure), headache and thromboembolic events (formation of blood clots in the blood vessels).

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).

Why is NeoRecormon authorised in the EU?

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

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

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

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

Other information about NeoRecormon

NeoRecormon received a marketing authorisation valid throughout the EU on 17 July 1997.

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

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