



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE  
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION\***  
**for**  
**EPOETIN ALFA HEXAL**

International Nonproprietary Name (INN): *epoetin alfa*

On 23 October 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion\*\* to recommend the variation to the terms of the marketing authorisation for the medicinal product Epoetin alfa Hexal. The Marketing Authorisation Holder for this medicinal product is Hexal Biotech Forschungs GmbH.

The CHMP adopted a new indication as follows:

“Epoetin alfa Hexal can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin (Hb) 10 – 13 g/dl [6.2 – 8.1 mmol/l], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).”

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Epoetin alfa Hexal will be as follows\*\*\*:

Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult and paediatric patients:

- Treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis (See section 4.4).
- Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis (See section 4.4).

Treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (e.g. cardiovascular status, pre-existing anaemia at the start of chemotherapy).

**Epoetin alfa Hexal can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of**

\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

\*\* Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

\*\*\* The text in bold represents the new or the amended indication.

**thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin (Hb) 10 – 13 g/dl [6.2 – 8.1 mmol/l], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).**

Epoetin alfa Hexal can be used to reduce exposure to allogeneic blood transfusions in adult non-iron deficient patients prior to major elective orthopaedic surgery, having a high perceived risk for transfusion complications. Use should be restricted to patients with moderate anaemia (e.g. Hb 10 - 13 g/dl) who do not have an autologous predonation programme available and with an expected blood loss of 900 to 1800 ml.