



26 July 2018
EMA/CHMP/503858/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Epoetin alfa Hexal

epoetin alfa

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Epoetin alfa Hexal. The marketing authorisation holder for this medicinal product is Hexal AG.

The CHMP adopted a new indication as follows:

“Epoetin alfa Hexal is indicated for the treatment of symptomatic anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml).”

For information, the full indications for Epoetin alfa Hexal will be as follows:²

“Epoetin alfa Hexal is indicated for the treatment of symptomatic anaemia associated with chronic renal failure (CRF):

- in adults and children aged 1 to 18 years on haemodialysis and adult patients on peritoneal dialysis (see section 4.4).
- in adults with renal insufficiency not yet undergoing dialysis for the treatment of severe anaemia of renal origin accompanied by clinical symptoms in patients (see section 4.4).

Epoetin alfa Hexal is indicated in adults 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) for the treatment of anaemia and reduction of transfusion requirements.

Epoetin alfa Hexal is indicated in adults in a predonation programme to increase the yield of autologous blood. Treatment should only be given to patients with moderate anaemia (haemoglobin [Hb] concentration range between 10 to 13 g/dl [6.2 to 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).

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² **New text in bold**



Epoetin alfa Hexal is indicated for non-iron deficient adults prior to major elective orthopaedic surgery, having a high perceived risk for transfusion complications to reduce exposure to allogeneic blood transfusions. Use should be restricted to patients with moderate anaemia (e.g. haemoglobin concentration range between 10 to 13 g/dl or 6.2 to 8.1 mmol/l) who do not have an autologous predonation programme available and with expected moderate blood loss (900 to 1,800 ml).

Epoetin alfa Hexal is indicated for the treatment of symptomatic anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml)."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.