



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for

MOZOBIL

International Nonproprietary Name (INN): *plerixafor*

On 29 May 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Mozobil, 20 mg/ml, solution for injection intended for the enhanced mobilisation of progenitor cells prior to stem cell transplantation in patients with lymphoma and multiple myeloma whose haematopoietic stem cells mobilise poorly. Mozobil was designated as an orphan medicinal product on 20 October 2004. The applicant for this medicinal product is Genzyme Europe B.V.

The active substance of Mozobil is plerixafor, an immunostimulant therapeutic class medicinal product (ATC code: L03AX16) that reversibly antagonizes the CXCR4 chemokine receptor and blocks binding of stromal cell-derived factor-1 α (SDF-1 α). This results in mobilization of haematopoietic stem cells (HSCs) to the peripheral blood where they can be collected for HSC transplantation.

The benefits with Mozobil in conjunction with G-CSF are the increased number of patients who reach a target number of cell mobilisation compared to G-CSF alone, as shown in randomized placebo-controlled trials in patients with lymphoma and multiple myeloma undergoing mobilisation for autologous HSC transplantation.

The most common side effects are diarrhoea, nausea (feeling sick), injection site redness or irritation.

A pharmacovigilance plan for Mozobil as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Mozobil is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly (see section 4.2 of SPC)”. It is proposed that Mozobil therapy should be initiated and supervised by a physician experienced in oncology and/or haematology. The mobilisation and apheresis procedures should be performed in collaboration with an oncology-haematology centre with acceptable experience in this field and where the monitoring of haematopoietic progenitor cells can be correctly performed.

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

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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 CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Mozobil and therefore recommends the granting of the marketing authorisation