EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 September 2014
EMA/CHMP/453326/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Egranli

balugrastim

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Egranli, 40 mg, solution for injection intended for prophylaxis against chemotherapy-induced neutropenia. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Egranli is balugrastim, an immunostimulating medicinal product (L03AA15) which regulates the production and release of functional neutrophils from the bone marrow.

The benefits with Egranli are its ability to reduce the severity of neutropenia and the incidence of febrile neutropenia following the administration of cytotoxic chemotherapy. The most common side effects are musculoskeletal pains, thrombocytopenia, headache, leucocytosis, skin reactions and increase in liver enzymes.

A pharmacovigilance plan for Egranli will be implemented as part of the marketing authorisation.

The approved indication is: "Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of myeloid leukaemia and myelodysplastic syndromes)".

It is proposed that Egranli treatment should be initiated and supervised by physicians experienced in oncology or haematology.

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

[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.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Egranli and therefore recommends the granting of the marketing authorisation.