



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Krystexxa

pegloticase

On 18 October 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Krystexxa, 8 mg/ml, concentrate for solution for infusion intended for *the treatment of severe debilitating chronic tophaceous gout in adult patients who may also have erosive joint involvement and who have failed to normalize serum uric acid with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these medicines are contraindicated*. The applicant for this medicinal product is Savient Pharma Ireland Ltd. 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 Krystexxa is pegloticase, an other antigout preparation (M04AK02) and is a polyethylene glycol (PEG)-modified recombinant mammalian uricase of the therapeutic class bi-uricolytic agent that reduce serum uric acid.

The benefits with Krystexxa are its ability to reduce serum uric acid undetectable level in patients who have failed to respond to conventional urate-lowering therapy (xanthine oxidase inhibitors or uricosuric agents). The most common side effects are infusion reactions/anaphylactic reactions, serious cardiac events, and gout flares have been identified.

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

The approved indication is: "*Krystexxa is indicated for the treatment of severe debilitating chronic tophaceous gout in adult patients who may also have erosive joint involvement and who have failed to normalize serum uric acid with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these medicines are contraindicated (see section 4.4)*."

The decision to treat with Krystexxa should be based on an on-going assessment of the benefits and risks for the individual patient (see section 4.4)." It is proposed that treatment with Krystexxa should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of severe refractory chronic gout.

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.



The medicinal product should be administered in a healthcare setting and by healthcare professionals prepared to manage anaphylaxis and infusion reactions. Close monitoring is required during the infusion and for at least 1 hour after the end of the infusion. Availability of resuscitation equipment must be ensured.

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.

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

Medicinal product no longer authorised