28 June 2018
EMA/CHMP/383566/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mepsevii

vestronidase alfa

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mepsevii, intended for the treatment of mucopolysaccharidosis type VII. Mepsevii was designated as an orphan medicinal product on 21 March 2012. The applicant for this medicinal product is Ultragenyx Germany GmbH.

Mepsevii will be available as 2 mg/ml concentrate for solution for infusion. The active substance of Mepsevii is vestronidase alfa, a recombinant form of human beta-glucuronidase (ATC code: A16AB18). Mepsevii is an enzyme replacement therapy intended to provide or supplement beta-glucuronidase, an enzyme that helps with the degradation of glycosaminoglycans and thus prevents their accumulation in various tissues in the body.

The benefits with Mepsevii are its ability to reduce glycosaminoglycan levels in the body. The most common side effects are anaphylactoid reaction, urticaria and infusion site swelling.

The full indication is:

"Mepsevii is indicated for the treatment of non-neurological manifestations of Mucopolysaccharidosis VII (MPS VII; Sly syndrome)."

It is proposed that treatment with Mepsevii should be supervised by a healthcare professional experienced in the management of patients with MPS VII or other inherited metabolic disorders.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact