9 October 2015
EMA/CVMP/484431/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Imrestor

International non-proprietary name (INN): pegbovigrastim

On 8 October 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Imrestor, solution for injection in a pre-filled syringe, intended as an aid in the herd management programme of dairy cows, to reduce the risk of clinical mastitis in cattle. The applicant for this veterinary medicinal product is Eli Lilly and Company Limited, UK.

The active substance of Imrestor is pegbovigrastim (ATCvet code QL03AA90), which is a modified form of the naturally occurring immunoregulatory cytokine bovine granulocyte colony stimulating factor (bG-CSF). Pegbovigrastim restores the normal neutrophil function to cattle during the periparturient period, thus reducing their susceptibility to clinical mastitis infections.

The benefit of Imrestor is, as an aid in the herd management programme, to reduce the risk of clinical mastitis in periparturient cows and heifers during the 30 days following calving. The most common adverse events are transient injection site reactions which resolve in 14 days.

Detailed conditions 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.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Imrestor and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact