9 October 2015
EMA/CVMP/484406/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Velactis

International non-proprietary name (INN): Cabergoline

On 8 October 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion2, recommending the granting of a marketing authorisation for the veterinary medicinal product, Velactis 1.12 mg/ml solution for injection for cattle (dairy cows).

Velactis is intended for use in the herd management programme of dairy cows as an aid in the abrupt drying-off. The applicant for this veterinary medicinal product is CEVA Santé Animale.

Velactis is a medicinal product containing cabergoline (ATCvet code QG02CB03) as active substance, which is a potent dopamine receptor agonist on D2 receptors, leading to the inhibition of prolactin and, consequently, to a reduction of milk production. The benefits of Velactis are its use in the herd management programme of dairy cows as an aid in the abrupt drying-off by reducing milk production; to reduce milk leakage at drying off, to reduce the risk of new intramammary infections during the dry period, and to reduce discomfort.

The most common adverse events are slight transient injection site reactions (mostly swellings) which may persist for at least 7 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 Velactis 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.

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