16 April 2010
EMA/CVMP/149474/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Suprelorin EMEA/V/C/109/X/005

International non-proprietary name (inn): deslorelin acetate

On 14 April 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the extension of the marketing authorisation for the veterinary medicinal product Suprelorin. The Applicant for this veterinary medicinal product is Virbac S.A.

Suprelorin is currently authorised as a 4.7 mg implant for dogs for the induction of temporary infertility for a minimum duration of 6 months in healthy, entire, sexually mature male dogs. The new extension concerns Suprelorin 9.4 mg implant for the induction of temporary infertility in healthy, intact male dogs for a minimum duration of 12 months.

The active substance of Suprelorin is deslorelin acetate, a Gonadotrophin-releasing hormone (GnRH), ATCvet code: QH01CA93.

The new presentations will be available as a sealed foil pouch in a cardboard carton containing either 2 or 5 implants and are to be administered subcutaneously in the loose skin on the back between the lower neck and the lumbar area using the implanter provided.

The most common side effects are a moderate swelling at the implant site which may be observed for 14 days.

The approved indication is: “For the induction of temporary infertility in healthy, entire, sexually mature male dogs.”

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 to risk balance for Suprelorin 9.4 mg and therefore recommends the granting of the extension of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.
** 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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