EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2020
EMA/CVMP/430527/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

OvuGel

International non-proprietary name (INN): triptorelin acetate

On 9 September 2020, 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 OvuGel, vaginal gel, intended for sows for reproduction. The applicant for this veterinary medicinal product is Vetoquinol S.A.

OvuGel is a hormonal medicinal product containing triptorelin acetate (ATCvet code: QH01CA97) as active substance. It is a synthetic analogue of gonadotropin releasing hormone (GnRH), stimulating the release of luteinizing hormone (LH) and follicle stimulating hormone (FSH), which then further stimulate the production of sex steroids and ovulation.

The benefits of OvuGel are its use for the synchronisation of ovulation in weaned sows to enable a single fixed-time artificial insemination. OvuGel is generally well tolerated in sows at the recommended dose; however, it is recommended that pregnant women should not handle the veterinary medicinal product, and that women of child-bearing age should handle the veterinary medicinal product with caution.

The full indication is: For the synchronisation of ovulation in weaned sows to enable a single fixed-time artificial insemination.

Detailed conditions for the use of this product are 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 OvuGel 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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