22 February 2019
EMA/CVMP/56532/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

ReproCyc ParvoFLEX

Common name: Porcine parvovirosis vaccine (inactivated)

On 21 February 2019, 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 ReproCyc ParvoFLEX, suspension for injection, intended for active immunisation of gilts and sows from the age of 5 months to protect progeny against transplacental infection caused by porcine parvovirus. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

ReproCyc ParvoFLEX is an immunological veterinary medicinal product containing porcine parvovirus strain 27a viral protein 2 (ATCvet code QI09AA02) as active substance.

The benefit of ReproCyc ParvoFLEX is the stimulation of active immunity in gilts and sows from 5 months of age resulting in the protection of progeny against transplacental infection caused by porcine parvovirus. The onset of immunity is from the start of the gestation period and the duration of immunity is 6 months.

ReproCyc ParvoFLEX is well tolerated at the recommended dose. The most common side effects are transient local reactions at the injection site (redness or swelling) which resolve within two to five days without treatment; an increase in body temperature after vaccination is common and resolves spontaneously within 24 to 48 hours.

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 ReproCyc ParvoFLEX 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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