7 October 2016
EMA/CVMP/585411/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

HALAGON

International non-proprietary name (INN): halofuginone

On 6 October 2016, 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 HALAGON an oral solution intended to prevent or reduce diarrhoea in newborn calves due to diagnosed *Cryptosporidium parvum*. The applicant for this veterinary medicinal product is Emdoka BVBA. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

HALAGON is an antiprotozoal medicinal product containing halofuginone lactate (ATCvet code QP51AX08) as active substance which prevents the growth of *Cryptosporidium parvum*. It also prevents it from forming oocysts, which are formed at a certain stage in the lifecycle of the parasite and are excreted in the faeces.

The benefits of HALAGON are its capacity of preventing and reducing diarrhoea due to diagnosed *Cryptosporidium parvum,* and reducing oocysts excretion in newborn calves. In very rare cases, an increase in the level of diarrhoea has been observed in treated animals. HALAGON is generally well tolerated at the recommended dose.

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 HALAGON 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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