7 December 2018
EMA/CVMP/788664/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Kriptazen

International non-proprietary name (INN): halofuginone

On 6 December 2018, 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 Kriptazen oral solution intended for use in calves. The applicant for this veterinary medicinal product is Virbac S.A.

Kriptazen 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.

Kriptazen is a generic of Halocur, which has been authorised in the EU since 29 October 1999. Studies have demonstrated the satisfactory quality of Kriptazen, and its bioequivalence to the reference product Halocur. A question and answer document on generic medicines can be found *here*.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Kriptazen and therefore recommends the granting of the marketing authorisation.

The full indication is: "In new born calves:

- Prevention of diarrhoea due to diagnosed *Cryptosporidium parvum*, in farms with history of cryptosporidiosis. Administration should start in the first 24 to 48 hours of age.
- Reduction of diarrhoea due to diagnosed *Cryptosporidium parvum*. Administration should start within 24 hours after the onset of diarrhoea.

In both cases, the reduction of oocysts excretion has been demonstrated."

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.

[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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