22 February 2019
EMA/CVMP/64773/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Forceris

International non-proprietary name (INN): toltrazuril / gleptoferron

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 Forceris 30 mg/ml + 133 mg/ml suspension for injection for piglets. The applicant for this veterinary medicinal product is Ceva Santé Animale.

Forceris is a fixed combination medicinal product containing toltrazuril and iron as gleptoferron (ATCvet code QP51AJ01) as the two active substances. Toltrazuril is an antiprotozoal agent which has anticoccidial activity. Iron is an essential micronutrient which plays a major role in the transport of oxygen via haemoglobin, as well as having a key role in many enzymes.

The benefits of Forceris are its efficacy in piglets for the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

Forceris is a fixed dose combination and should only be used in piglets which are at risk of developing coccidiosis, but taking into consideration that these animals also need to be treated with iron in their first days of life.

Forceris is generally well tolerated at the recommended dose. Adverse reactions (an increased susceptibility for (systemic) bacterial disease, arthritis, abscess formation, transient reduced erythrocyte count and haematocrit and haemoglobin concentrations without clinical signs, and mortality) are only seen at overdoses.

The full indication is:
"For the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in piglets in farms with a confirmed history of coccidiosis caused by *Cystoisospora suis.*"

[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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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 Forceris and therefore recommends the granting of the marketing authorisation.