22 March 2019
EMA/CVMP/98703/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Baycox Iron

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

On 21 March 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 Baycox Iron 36 mg/ml + 182 mg/ml suspension for injection for piglets. The applicant for this veterinary medicinal product is Bayer Animal Health GmbH.

Baycox Iron is a fixed combination medicinal product containing toltrazuril and iron, as gleptoferron, (ATCvet code QP51AJ51) 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 Baycox Iron are its efficacy for the concurrent prevention of clinical signs of coccidiosis (such as diarrhoea) in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis,* and prevention of iron deficiency anaemia.

Baycox Iron is a fixed dose combination product and should only be used in neonatal 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.

Baycox Iron is generally well tolerated at the recommended dose. The most common side effects are transient discolouration of the tissue and/or slight swelling which may be observed commonly at the site of injection. Other adverse reactions *(*apathy, dyspnoea, elevated rectal temperatures, reddening of the skin, ataxia, and/or adverse events of the legs or joints (such as polyarthritis)) are only seen at overdoses.

The full indication is:

“For the concurrent prevention of clinical signs of coccidiosis (such as diarrhoea) in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*, and prevention of iron deficiency anaemia.”

[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 Baycox Iron and therefore recommends the granting of the marketing authorisation.