IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Coxx-Kure 50 mg/ml oral suspension for piglets and calves

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Coxx-Kure 50 mg/ml oral suspension for piglets and calves.
Active substance	Toltrazuril
Marketing Authorisation Holder	Laprovet, 7 rue du Tertreau, Arche D'Oé 2, 37390 Notre Dame D'Oé, France
Legal basis of application	Article 13.1 of Directive 2001/82/EC, as amended (a generic application).
Date of Authorisation	5th January 2015
Target species	Piglets and Calves
Indication for use	Piglets: For the prevention of clinical signs of coccidiosis in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Isospora suis*. Calves: For the prevention of clinical signs of coccidiosis and reduction of coccidian shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis, caused by *Eimeria bovis* or *Eimeria zuernii*.
ATCvet code	QP51AJ01.

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I SCIENTIFIC OVERVIEW

This product is identical in formulation to that of Cevazuril 50 mg/ml oral suspension for piglets and calves (VPA 10815/007/001 – Ceva Santé Animale) which was authorised in Ireland on 25th June 2010 following procedure number FR/V/0195/001/DC. As such, this is considered to be a duplicate application.

Consequently, the reader is referred to the publicly available assessment report for Cevazuril 50 mg/ml oral suspension for piglets and calves.

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II QUALITY ASPECTS

See Section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See Section I.

III SAFETY ASSESSMENT

See Section I.

IV CLINICAL ASSESSMENT (EFFICACY)

See Section I.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Changes:

Quality Changes

Summary of change (Application number)	**Approval date**
Change in the (invented) name of the medicinal product: for Nationally Authorised Products A.2.B (CRN 7021943)	dd/mmmm/yyyy