IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Milbotyl 300 mg/ml Solution for Injection

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0236/001/DC
Name, strength and pharmaceutical form	Milbotyl 300 mg/ml solution for injection
Active substance(s)	Tilmicosin
Marketing Authorisation Holder	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland
Legal basis of application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of Authorisation	25 November 2009
Target species	Cattle and sheep
Indication for use	For the treatment of pneumonia in cattle and sheep, associated with *Pasteurella heamolytica, Pasteurella multocida* and other micro-organisms sensitive to Tilmicosin. For the treatment of ovine mastitis associated with *Staphylococcus* aureus and *Mycoplasma agalactiae.* For the treatment of interdigital necrobacillosis in cattle (bovine pododermatitis, foul in the foot).
ATCvet code	QJ01FA91
Concerned Member States	UK

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

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 slight reactions observed are indicated in the SPC.
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

A. Qualitative and Quantitative Particulars

The product contains the active substance tilmicosin 300 mg/ml and excipients propylene glycol, phosphoric acid and water for injections.

The container/closure system consists of an amber glass vial closed with a bromobutyl rubber stopper.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is tilmicosin, an established active substance described in the United States Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

Not applicable

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The in-use shelf-life of the broached product is supported by the data provided.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.ASafety Testing<?xml:namespace prefix = "o" ns = "urn:schemas-microsoft-com:office:office" />

The application is made in accordance with Article 13(1) of Council Directive 2001/82/EC (as amended), a generic application.

Based on the arguments/data presented, it is accepted that the test and reference products can be considered equivalent, that exemption from the requirement for in vivo bioequivalence data is justified and that the safety profile (with respect to the target species and the user) of both the test and reference product will be the same. The user safety statements proposed for inclusion on the SPC of the test product reflect those agreed for the reference product and are considered appropriate.

It is accepted that the product, under normal conditions of use, will not present an unacceptable risk to the environment.

III.B Residues Documentation

The application is made in accordance with Article 13(1) of Council Directive 2001/82/EC (as amended), a generic application.

Based on the arguments/data presented, it is accepted that the test and reference products can be considered equivalent and that exemption from the requirement for in vivo bioequivalence data is justified.

It is accepted that there should be no difference between products with respect to residue depletion from tissues. Therefore, the absence of confirmatory residue studies is justified and the withdrawal periods authorised for the reference product can be applied to the generic product.

IV CLINICAL ASSESSMENT (EFFICACY)

This application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Based on the arguments/data presented, it is accepted that the test and reference products can be considered equivalent, that exemption from the requirement for in vivo bioequivalence data is justified and that the efficacy profile of both the test and reference product will be the same. It should be noted that the proposed indications and posology for the test product are identical to the authorised indications and posology of the reference product in the RMS.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

Further, given the similarity in formulations, it is accepted that tolerance in the target species will be similar for both formulations: the absence of target animal safety studies is justified.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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:

None.