Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Tulazzin 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep

Date Created: January 2021

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Tulazzin 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep
Applicant	SKANS Healthcare Ltd, 222 Mountbatten Close, Ashton-on-Ribble, Preston, PR2 2XF
Active substance	Tulathromycin
ATC Vetcode	QJ01FA94
Target species	Cattle, Pigs, Sheep
Indication for use	***Cattle*** Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* sensitive to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis* sensitive to tulathromycin. ***Pigs*** Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis* and *Bordetella bronchiseptica* sensitive to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Tulazzin should only be used if pigs are expected to develop the disease within 2–3 days. Sheep Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	2nd December 2020

I. SCIENTIFIC OVERVIEW

This was an application for a generic product, Tulazzin 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep, submitted in accordance with Article 13 (1) of Directive 2001/82/EC, as amended by 2004/28/EC. The product is indicated for use in cattle, pigs and sheep, for a large variety of organisms, as described above.

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, any reactions observed are indicated in the SPC.[1] 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 [2] 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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 100 mg/ml tulathromycin and the excipients monothioglycerol, propylene glycol, citric acid, hydrochloric acid, sodium hydroxide and water for injections.

The container/closure system consists of clear Type I glass vials, with a fluoropolymer coated chlorobutyl stopper and an aluminum overseal.

Pack size: Cardboard box containing one vial. Vial sizes: 50 ml, 100 ml and 250 ml. The particulars of the containers and controls performed are provided and conform to the regulation.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The choice of the formulation and the presence of preservative, (monothioglycerol), are justified.

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of a simple dissolution and adjustment process, followed by quality control and aseptic filling into vials.

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

II.C. Control of Starting Materials

The active substance is tulathromycin an established active substance, not listed in a 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.

All excipients with the exception of monothioglycerol which is tested using the pharmacopoeia of the United States Formulary, have an EU monograph in the European Pharmacopoeia. Packaging is suitably controlled.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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. Control tests on the finished product are those for: appearance, identification and assay of monothioglycerol, the active substance and related substances, clarity and colour of solution, extractable volume, impurities, bacterial endotoxin test and sterility.

II.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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.
This veterinary medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Due to the nature of the application, toxicological and pharmacological studies were not required. A user risk assessment and environmental risk assessment were submitted.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the product presents an acceptable risk to users when used in accordance with the SPC and product literature.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- Tulathromycin is irritating to eyes. In case of accidental eye exposure, flush the eyes immediately with clean water.
- Tulathromycin may cause sensitization by skin contact. In case of accidental spillage onto skin, wash the skin immediately with soap and

water.

- This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to macrolides, such as tulathromycin, should avoid contact with the product.
- Wash hands after use.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

The ERA concludes in Phase I at Question 17 of the decision tree on the basis that the PEC_{soil} value calculated for each category of target animal species is below the threshold value (100 µg/kg) for progressing to a Phase II assessment. The PEC_{soil} values have been verified and the conclusion of the applicant is supported. The disposal advice is in accordance with current guidance and the product is not expected to pose a risk for the environment when used in accordance with the recommendations included in the proposed SPC.

III.B.2 Residues documentation

Residue Studies

Due to the nature of the application, no additional residue depletion studies were conducted.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Due to the nature of the application, no additional data were required for this section.

Tolerance in the Target Species

Due to the nature of the application, no additional data were required for this section.

Resistance

Adequate warnings and precautions appear on the product literature.

IV.II. Clinical Documentation

Due to the nature of the application, no additional data were required for this section.

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 of the product is favourable.

MODULE 4

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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