IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Tuloxxin 100 mg/ml solution for injection for cattle, pigs and sheep

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PRODUCT SUMMARY

EU Procedure number	IE/V/0396/001/DC
Name, strength and pharmaceutical form	Tuloxxin 100 mg/ml solution for injection for cattle, pigs and sheep
Active substance	Tulathromycin
Applicant	Krka, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of Authorisation	N/a
Target species	Cattle, pigs and sheep
Indication for use	<u>Cattle</u> Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* susceptible 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* susceptible to tulathromycin. <u>Pigs</u> Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida, Mycoplasma hyopneumoniae,Haemophilus parasuis* and *Bordetella bronchiseptica* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2–3 days. <u>Sheep</u> Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.
ATCvet code	QJ01FA94
Concerned Member States	BE, BG, CZ, DE, EE, EL, ES, FR, HR, HU, IT, LT, LV, NL, PL, PT, RO, SI, SK, 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.

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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 tulathromycin (100 mg/ml) as the active substance and the excipients monothioglycerol, propylene glycol, citric acid, hydrochloric acid, sodium hydroxide and water for injections.
The container/closure system is a Type I clear glass bottle containing 50 ml, 100 ml or 250 ml closed with Type I chlorobutyl/butyl film laminated rubber stoppers and sealed with aluminium caps.
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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is tulathromycin, an established active substance. 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 has 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 has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

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F. Stability

Stability data on the active substance has 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 has 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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application was submitted in accordance with Article 13(1) of Directive 2001/82/EC (a "generic" veterinary medicinal product). The reference veterinary medicinal product is Draxxin 100 mg/ml solution for injection for cattle, pigs and sheep containing tulathromycin as active substance.

Pharmacological Studies

This is a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended. Based on the information provided, bioequivalence with a reference product can be assumed. Consequently, the results of safety tests or of pre-clinical and clinical trials are not required.

Toxicological Studies

As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted, results of toxicological tests are not required.

The safety aspects of this product are expected to be identical to those of the reference product.

Warnings and precautions as listed on the product literature are broadly in line with those of the reference product.

User Safety

The user safety statements are broadly in line with those of the reference product and are acceptable.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:
Tulathromycin is irritating to eyes. In case of accidental eye exposure, flush the eyes immediately with clean water.
Tulathromycin may cause sensitisation by skin contact. In case of accidental spillage onto skin, wash the skin immediately with soap and water. 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 Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to CVMP/VICH guidelines.

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues Documentation

As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted, studies investigating the depletion of residues are not required.

The active substance tulathromycin is included in table 1 of the Annex to Commission Regulation (EU) No. 37/2010.

The withdrawal periods are identical to those approved for the reference product and are considered adequate to ensure consumer safety.

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IV. CLINICAL ASSESSMENT

As this is a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended, and as bioequivalence with a reference product is accepted, efficacy studies are not required.

The efficacy claims for this product are expected to be equivalent to those of the reference product. In addition, it is considered that the risk to the target species will be similar for both the test and the reference products. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

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.

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