DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

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PRODUCT SUMMARY

EU procedure number	ES/V/0428/001/DC
Name, strength and pharmaceutical form	DAXTON 100 mg/ml solution for injection for cattle, pigs and sheep
Applicant	Cenavisa S.L. C/dels Boters 4 Reus Tarragona
Active substance(s)	Tulathromycin
ATC vetcode	QJ01FA94
Target species	cattle, pigs and sheep
Indication for use	Cattle 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 group must be established before the product is used. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin. Pigs 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 group must be established before the product is used. This veterinary medicinal product 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.

DAXTON 100 mg/ml solution for injection for cattle, pigs and sheep	ES/V/0428/001/DC
Cenavisa S.L.	DCP
Publicly available assessment report	

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	DCP application in accordance with Article 18 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018
Reference product (RP)	DRAXXIN 100 mg/ml solution for injection
Marketing authorisation holder	Zoetis Belgium SA
MS where the RP is or has been authorised	
Marketing authorisation number	EU013 IP
EU procedure number	EMEA/V/C/000077
Date of authorisation	11/11/2003
Date of completion of the original decentralised procedure	10/07/2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BE, BG, CZ, HR, DK, EE, EL, HU, IT, LV, LT, PL, RO
Concerned Member States for subsequent recognition procedure	N/A

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

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

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

2.A. Product description

The VMP contains tulathromycin as active substance (100 mg/mL) and monothioglycerol as antioxidant. Other ingredients are citric acid, propylene glycol, hydrochloric acid, sodium hydroxide and water for injections.

The container/closure system is Type II clear glass vial with a bromobutyl stopper and an aluminium overseal.

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

2.B. Description of the manufacturing method

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

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

2.C. Production and control of starting materials

The active substance is Tulathromycin, an established active substance which is not described in 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.

The information on the active substance is provided according to the Active Substance Master File (ASMF) procedure.

Satisfactory TSE information has been provided in compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

D. Control on intermediate products

Not applicable.

2.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 VMP.

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.

2.F. Stability tests

Stability data on the active substance tulathromycin 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 VMP throughout its shelf life (3 years) when stored under the approved conditions.

Data submitted on in-use stability studies are considered sufficient to support an in-use shelf life of 28 days after broaching.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

The safety aspects of this VMP are essential similar to the reference VMP.

Warnings and precautions as listed on the product literature are similar as those of the reference VMP and are adequate to ensure safety of the product to users, the environment, and consumers.

3.A. Safety tests

Given that the requirements of Article 18 of Regulation (EC) 2019/6 are fulfilled, and bioequivalence with a reference VMP has been demonstrated, the safety profile of the reference product can be assumed.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that no greater risk for the user is expected to arise for the candidate formulation when compared to the reference formulation.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil is less than 100 µg/kg.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted on the basis that bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Tulathromycin is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Tulathromycin	(2R,3S,4R,5R,8R,10R, 11R,12S,13S,14R)-2- ethyl-3,4,10,13-tetrahydroxy3,5,8,10,12,14-hexamethyl-11- [[3,4,6-trideoxy-3- (dimethylamino)-ß-D-xylohexopyranosyl]oxy]-1-oxa-6-	Bovine	300 µg/kg 200 µg/kg 4500 µg/kg 3000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals producing milk for human consumption
		Porcine	800 µg/kg 300 µg/kg	Muscle Skin and fat	

	azacyclopentadecan15-one expressed as tulathromycin equivalents		4000 µg/kg 8000 µg/kg	in natural proportions Liver Kidney	
		Ovine, caprine	450 µg/kg 250 µg/kg 5400 µg/kg 1800 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Cattle (meat and offal): 22 days.

Pigs (meat and offal): 13 days.

Sheep (meat and offal): 16 days.

Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

4.A. Pre-Clinical Studies

Development of resistance and related risk in animals

The applicant provided recent bibliographical information on antimicrobial resistance (MIC data) for pathogens of clinical relevance for the claimed indications in the target species. The bibliography / information provided suggests that the susceptibility/resistance situation has not significantly changed since the authorisation of the reference VMP.

Adequate warnings and precautions appear on the product literature.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

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

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None.