DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

VETDRAXX 100 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND SHEEP

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0391/001/DC
Name, strength and pharmaceutical form	VETDRAX 100 mg/ml solution for injection for cattle, pigs and sheep
Applicant	VETPHARMA ANIMAL HEALTH, S.L.
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 veterinary medicinal 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 veterinary medicinal product is used. The 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.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	03.03.21
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, DK, FR, DE, EL, HU, IT, NL, PL, PT, RO, UK(NI)

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 risk/benefit 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 active substance, monothioglycerol as antioxidant and the excipients citric acid, propylene glycol, hydrochloric acid dilute, sodium hydroxide and water for injections. The product is a clear colourless to slightly yellow solution, free from visible particles.

The veterinary medicinal product is presented in colourless glass (type I Ph. Eur.) vials of 100 ml and 250 ml closed with a bromobutyl rubber stopper covered with a fluorinated polymer coating and sealed with aluminium cap.

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 from 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 tulathromycin, an established active substance which is not described 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.

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 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 product throughout its shelf life (30 months) 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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 and bioequivalence with the reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

As this is a generic application according to Article 13 and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

User Safety

Although this is a generic application according to Article 13 and bioequivalence with the reference product has been demonstrated, the applicant has provided a brief user safety assessment broadly in accordance with the relevant guideline.

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

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 in all scenarios the initial predicted environmental concentrations in soil is less than 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because bioequivalence to the reference product has been demonstrated and there are no differences in the composition of the candidate product when compared to the reference product.

MRLs

The active substance Tulathromycin is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010.

MRLs are listed below:

	Porcine	Bovine	Ovine
Muscle	800 µg/kg	300 µg/kg	450 µg/kg
Liver	4000 µg/kg	4500 µg/kg	5400 µg/kg
Kidney	8000 µg/kg	3000 µg/kg	1800 µg/kg
Fat / skin	300 µg/kg	200 µg/kg	250 µg/kg
Milk	Not for use in animals from which milk is produced for human consumption.		

Withdrawal Periods

Based on the data provided above, a withdrawal period of 22 days for meat and offal in cattle, 13 days for meat and offal in pigs and 16 days for meat and offal in sheep are justified. The product is not authorised for use in animals producing milk for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Resistance

The bibliography / information provided suggests that there does not seem to be a potential concern regarding the development and spread of antimicrobial resistance to tulathromycin in the target pathogens. The resistance status is considered to be sufficiently documented.

Adequate warnings and precautions appear on the product literature.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 veterinary Heads of Agencies website (www.hma.eu).

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.

None