DEPARTAMENTO DE
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VETERINARIOS

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(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FLORTEKXIN 300/16.5 MG/ML SOLUTION FOR INJECTION FOR CATTLE
(Florfenicol, flunixin)

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PRODUCT SUMMARY

EU procedure number	ES/V/0427/001/DC
Name, strength and pharmaceutical form	FLORTEKXIN 300/16.5 MG/ML SOLUTION FOR INJECTION FOR CATTLE
Applicant	Laboratorios Karizoo S.A. Carrer Mas Den Pujades 11-12 Poligono Industrial La Borda - Caldes De Montbui 08140 – Barcelona - Spain
Active substance(s)	Florfenicol, flunixin
ATC vetcode	QJ01BA99
Target species	Cattle
Indication for use	Treatment of respiratory infections caused by *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma bovis*, associated with pyrexia.

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*	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP)	Resflor solution for injection
Marketing authorisation holder	Merck Sharp & Dohme Animal Health S.L.
MS where the RP is or has been authorised	N/A
Marketing authorisation number	1703 ESP
EU procedure number	N/A
Date of authorisation	27/10/2006
Date of completion of the original decentralised procedure	20/12/2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BE, DE, FR, IE, IT, NL, PT
Concerned Member States for subsequent recognition procedure	N/A
Withdrawn CMS during original <mutual recognition> <decentralised><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 300.00 mg/ml of florfenicol and 16.50 mg/ml of flunixin meglumine and the excipients N-methylpyrrolidone, propylene glycol, citric acid and macrogol 300.

The container/closure system is a polypropylene/ethylene vinyl alcohol/polypropylene multi-layer (COEX) vial closed with bromobutyl rubber stopper type I and aluminium cap with plastic lid.

The choice of the formulation and the presence of preservative are justified.

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 flunixin meglumine is an established substance described in the European Pharmacopeia. The active substance florfenicol is not described in the European Pharmacopoeia. Both substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with the specifications have been provided.

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

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 substances 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 when stored under the approved conditions.

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

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 pharmacological tests are not required.

Toxicological studies

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 toxicological tests are not required.

User safety

The user safety aspects of this product are identical to the reference product. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

In accordance with article 18(7) of the Regulation 2019/6 and the CVMP Reflection Paper on the interpretation of the mentioned article, the applicant must provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment where the marketing authorisation for the reference veterinary medicinal product was granted before 1 October 2005. The reference VMP was registered on 26th October 2006. In consequence, the conditions set in the above-mentioned RP for not providing an ERA are fulfilled. No unacceptable risks for the environment are expected when the product is used, handled and disposed according to the information included in the SPC.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is a generic application according to Article 18, and bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Florfenicol and Flunixin are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision	Therapeutic Classification
Florfenicol	Sum of florfenicol and its metabolites measured as	Bovine, ovine, caprine	200 µg/kg 3 000 µg/kg 300 µg/kg	Muscle Liver Kidney	Not for animals from which milk is produced for human	Anti-infectious agents/Antibiotics

	florfenicolamine				consumption.	
Flunixin	Flunixin	Bovine	20 µg/kg 30 µg/kg 300 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Anti-inflammatory agents/Nonsteroidal anti-inflammatory agents
	5-Hydroxyflunixin		40 µg/kg	Milk		

Withdrawal Periods

The same withdrawal periods than the reference product are proposed:

Meat and offal: 46 days.
Milk: 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.

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.