IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Selectan Oral 23 mg/ml solution for use in drinking water for pigs

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0263/001/DC
Name, strength and pharmaceutical form	SELECTAN ORAL 23 mg/ml solution for use in drinking water for pigs
Active substance(s)	Florfenicol
Applicant	LABORATORIOS HIPRA, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	23rd March 2011
Target species	Swine
Indication for use	Treatment and prevention at the group level where clinical signs are present of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.
ATCvet code	QJ01BA90
Concerned Member States	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FR, HU, IT, LT, LU, NL, PL, PT, RO, 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.

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 23 mg/ml florfenicol and macrogol 300.

The container is a 5-L HDPE-barrel closed with a HDPE plastic screw-on caps and a polyethylene safety seal.

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 florfenicol which is not described in the European or British Veterinary 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.

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 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 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

Not applicable. Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016)) is accepted because the product is an oral solution for administration in drinking water containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the test product is bioequivalent to Nuflor Drinking Water Concentrate for Swine, it is accepted that safety (in terms of basic pharmacological and toxicological properties) will be similar to that of the reference product.

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 product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required. The phase II assessment concluded that when used in accordance with the proposed recommendations for use, the product does not pose an unacceptable risk to micro-organisms, plants, earthworms, aquatic invertebrates or fish.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because the product is an oral solution for administration in drinking water containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance. The withdrawal period for Selectan Oral is the same as that authorised for the reference product.

MRLs

Florfenicol is listed in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010 (O.J 20.1.2010, L15/30). The marker substance is the sum of florfenicol and its metabolites measured as flofenicol-amine.

MRLs are listed below:

	Swine
Muscle	300 µg/kg
Liver	2000 µg/kg
Kidney	500 µg/kg
Fat / skin	500 µg/kg

Withdrawal Periods

Based on the justification provided above, a withdrawal period of 20 days for meat in swine is justified.

IV CLINICAL ASSESSMENT (EFFICACY)

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016)) is accepted because the product is an oral solution for administration in drinking water containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the test product is bioequivalent to Nuflor Drinking Water Concentrate for Swine, it is accepted that the efficacy profile will be similar to that of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

A target animal safety study specific to the test product has not been presented with the application. Given that: The product is an oral dose form,

Bioequivalence with the reference product Nuflor Drinking Water Concentrate for Swine is accepted

The proposed indications and posology for the test product are identical to the authorised indications and posology of the reference product.

The toxicological profile of the active substance is well known

The excipient is recognised as being safe at the quantities likely to be ingested by the target animal

The impurity profile in the formulation is satisfactory, the absence of tolerance studies specific to the test product can be accepted.

It is accepted that the target animal safety profile of the test product will be the same as that of the reference product. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

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

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