IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Strantel Plus XL Tablets For Dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0273/002/MR
Name, strength and pharmaceutical form	Strantel Plus XL for Dogs
Active substance(s)	Praziquantel Pyrantel Embonate Febantel
Applicant	Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Galway, Ireland
Legal basis of application	A hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of procedure	25/09/2013
Target species	Dog
Indication for use	In adult dogs: Treatment of mixed infections by nematodes and cestodes of the following species **Nematodes:** **Ascarids:** *Toxocara canis*, *Toxascaris leonina*(adult and late immature forms). **Hookworms:** *Uncinaria stenocephala*, *Ancylostoma caninum*(adults). **Whipworms:***Trichuris vulpis*(adults). **Cestodes:** **Tapeworms:** *Echinococcus*species, *(E. granulosus, E. multilocularis),* *Taenia*species, *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum*(adult and immature forms).
ATCvet code	QP52AA51
Concerned Member States	FR, CZ, FI, NL, SE, SK, PT, ES & 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 product is safe for the user 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 175 mg praziquantel, 504 mg pyrantel embonate, 525 mg febantel, and the excipients microcrystalline cellulose, lactose monohydrate, sodium laurilsulphate, magnesium stearate, croscarmellose sodium, colloidal anhydrous silica and pork flavour. The tablets are packaged in blister packs.
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 substances are established active substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with the specifications 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.

F. Stability

Stability data on the active substances 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)

III.A Safety Testing

Pharmacological Studies

Strantel Plus XL tablet is a pro rata formulation of Strantel Plus tablets. Strantel Plus XL has been formulated to have the same active substances and excipients in the same ratio, as the authorised product, Strantel Plus. The applicant conducted an *in vitro*dissolution study between the test product and the authorised product, Strantel Plus. This study confirmed comparable dissolution for Strantel Plus and Strantel Plus XL in all dissolution media for all active substances. Based on *in vitro*dissolution it is accepted that the safety and efficacy profile for both Strantel Plus XL and Strantel Plus tablets will be similar.

Toxicological Studies

Based on *in vitro*dissolution it is accepted that the safety profile for both Strantel Plus XL and Strantel Plus tablets will be similar. Refer to the assessment report for Strantel Plus tablets.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not present any greater risk to the user relative to that posed by the authorised product, Strantel Plus. The product is presented in blister and foil packaging in order to minimise the risk of exposure to children.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Pharmacology

Strantel Plus XL tablet is a pro rata formulation of Strantel Plus tablets. Strantel Plus XL has been formulated to have the same active substances and excipients in the same ratio, as the authorised product, Strantel Plus. The applicant conducted an *in vitro* dissolution study between the test product and the authorised product, Strantel Plus. This study confirmed comparable dissolution for Strantel Plus and Strantel Plus XL in all dissolution media for all active substances. Based on *in vitro* dissolution it is accepted that the safety and efficacy profile for both Strantel Plus XL and Strantel Plus tablets will be similar.

Tolerance in the Target Species of Animals

Given that:
·Strantel Plus XL has been formulated to have the same composition, pro rata, in terms of active substances and excipients, as the authorised product, Strantel Plus,
·*In vitro* dissolution profiles for the test and authorised products are comparable in all dissolution media for all active substances indicating similar rate of release of active substances following ingestion, and
·The proposed conditions of use of Strantel Plus XL are identical to those of the authorised product, Strantel Plus, (there are differences with respect to the weight of animal to be treated, but all animals regardless of weight will receive the same mg/kg dose of active),
it can be assumed that Strantel Plus XL is unlikely to present any greater risk to the target animal relative to that posed by the product, Strantel Plus.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Based on *in vitro* dissolution it is accepted that the efficacy profile for both Strantel Plus XL and Strantel Plus tablets will be similar.
The efficacy claims for this product reflect those authorised for Strantel Plus and can be accepted.

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.