

IPAR



Publicly Available Assessment Report for a **Veterinary Medicinal Product**

Exitel Plus XL Tablets For Dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0242/002/X/001
Name, strength and pharmaceutical form	Exitel Plus XL Tablets For Dogs
Active substances	Praziquantel, Pyrantel embonate, Febantel
Applicant	Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Co. Galway, Ireland.
Legal basis of application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of procedure	27th June 2012
Target species	Dog
Indication for use	Treatment of mixed infections by nematodes and cestodes
ATCvet code	QP52AA51
Concerned Member States	AT, DE, EE, EL, IT, NL, RO, 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 and 525 mg of febantel as active substances and the excipients lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, croscarmellose sodium, sodium laurilsulfate and pork flavour.

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 for each active substance.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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

The stability of the active substances has been demonstrated.

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

Exitel Plus XL tablet is a pro rata formulation of Exitel Plus tablets. Exitel Plus XL has been formulated to have the same active substances and excipients in the same ratio, as the authorised product, Exitel Plus. The applicant conducted an *in vitro* dissolution study between the test product and the authorised product, Exitel Plus. This study confirmed comparable dissolution for Exitel Plus and Exitel Plus XL in all dissolution media for all active substances. Based on *in*

in vitro dissolution it is accepted that the safety and efficacy profile for both Exitel Plus XL and Exitel Plus tablets will be similar.

Toxicological Studies

Based on *in vitro* dissolution it is accepted that the safety profile for both Exitel Plus XL and Exitel Plus tablets will be similar.

Refer to the assessment report for Exitel 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, Exitel 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 (EFFICACY)

Pharmacology

Exitel Plus XL tablet is a pro rata formulation of Exitel Plus tablets. Exitel Plus XL has been formulated to have the same active substances and excipients in the same ratio, as the authorised product, Exitel Plus. The applicant conducted an *in vitro* dissolution study between the test product and the authorised product, Exitel Plus. This study confirmed comparable dissolution for Exitel Plus and Exitel 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 Exitel Plus XL and Exitel Plus tablets will be similar.

Tolerance in the Target Species of Animals

Given that:

- Exitel Plus XL has been formulated to have the same composition, pro rata, in terms of active substances and excipients, as the authorised product, Exitel 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 Exitel Plus XL are identical to those of the authorised product, Exitel 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 Exitel Plus XL is unlikely to present any greater risk to the target animal relative to that posed by the product, Exitel 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 Exitel Plus XL and Exitel Plus tablets will be similar.

The efficacy claims for this product reflect those authorised for Exitel 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.