IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Drontal Dog Tasty Bone XL

"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/0335/002/DC
Name, strength and pharmaceutical form	Drontal Dog Tasty Bone XL 525/504/175 mg tablets
Active substance(s)	Febantel/Pyrantel Embonate/Praziquantel
Applicant	Bayer Limited Animal Health Division The Atrium Dublin 18 Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of Authorisation	
Target species	Dogs

Indication for use	Treatment of mixed infections by nematodes and cestodes of the following species: Roundworms: Ascarids (adult and late immature forms) : *Toxocara canis, Toxascaris leonina* Hookworms (adults): *Uncinaria stenocephala, Ancylostoma caninum* Whipworms (adults): *Trichuris vulpis* Tapeworms (adult and immature forms): *Echinococcus granulosus, Echinococcus multilocularis, Dipylidium caninum, Taenia*spp.
ATCvet code	QP52AA51
Concerned Member States	AT, DE, DK, FI, FR, IS, IT, NL, NO, SE, 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 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 525 mg febantel, 175 mg pyrantel (equivalent to 504 mg pyrantel embonate) and 175 mg praziquantel per tablet and the excipients maize starch, lactose monohydrate, microcrystalline cellulose, povidone K25, magnesium stearate, sodium laurilsulfate, colloidal anhydrous silica, croscarmellose sodium and meat flavour.
The product is presented in blisters formed from PA/Alu/PE foil and sealed with Alu/PE foil.
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 febantel, pyrantel embonate and praziquantel which 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 specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.
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

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)

This application was submitted in accordance with Article 13.1 of Directive 2001/82/EC – an application for a generic veterinary medicinal product.

III.A Safety Testing

Bioequivalence

The applicant claimed that the candidate formulation is bioequivalent to the reference formulation (Drontal Plus Flavour Bone-Shaped tablets as authorised in the RMS (VPA 10021/014/004)).
Results of comparative dissolution studies were provided in support of a waiver from the requirement to demonstrate *in-vivo* bioequivalence between the candidate and reference product formulations. Bioequivalence between candidate and reference product formulations was accepted based upon the results of the *in-vitro* dissolution study data.

Pharmacological Studies & Toxicological Studies

The applicant claimed that the candidate formulation is bioequivalent to the reference formulation as authorised in the RMS and consequently, referred to the safety and toxicological data included in the dossier of the reference product.
The omission of safety and toxicological data for the candidate formulation was accepted and it was concluded that no differences in safety and toxicity between candidate and reference products are to be expected.

User Safety

A user safety assessment assessing potential risks to the user of the higher strength candidate formulation (compared to the reference product formulation) was provided. Based on the information provided, it was concluded that a potential risk for the user may exist following accidental ingestion of a tablet by a child.

Consequently, appropriate risk mitigation measures/advice have been included in the product literature to help mitigate against this risk and this is considered appropriate to ensure safety of the product for the user.
It was accepted that the product will not present an unacceptable risk for the user when stored, handled, used and disposed of in accordance with the recommendations included in the SPC.

Environmental Risk Assessment

Phase I

An environmental impact assessment was provided, as required by the legislation.
The environmental risk assessment can stop in Phase I because the product will only be used in individual non-food producing animals.
It was accepted that the product will not present an unacceptable risk for the environment when stored, handled, used and disposed of in accordance with the recommendations included in the SPC.
Warnings and precautions as listed on the product literature are in line with those of the reference product and are considered adequate to ensure safety of the product to users and the environment.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies Pharmacology

No pharmacological data was provided.
The applicant claimed that the candidate formulation is bioequivalent to the reference formulation as authorised in the RMS and consequently, referred to the pre-clinical data included in the dossier of the reference product. This was considered acceptable given the legal basis of the application. ***Tolerance in the Target Species of Animals***

No target animal tolerance data was provided.
The applicant claimed that the candidate formulation is bioequivalent to the reference formulation as authorised in the RMS and consequently, referred to the pre-clinical data included in the dossier of the reference product. This was considered acceptable given the legal basis of the application.

IV.B Clinical Studies

Laboratory Trials & Field Trials

No data provided.
The applicant claimed that the candidate formulation is bioequivalent to the reference formulation as authorised in the RMS and consequently, referred to the clinical data included in the dossier of the reference product. This was considered acceptable given the legal basis of the application.

The omission of preclinical and clinical data for the candidate formulation was accepted and it was concluded that no difference in efficacy between candidate and reference products is to be expected.
It was accepted that the candidate formulation will be as efficacious as the reference product when stored, handled and used as recommended in the SPC.

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.
None