IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Prazpronto 60 mg Spot-on solution for large cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0633/003/DX/001
Name, strength and pharmaceutical form	Prazpronto 60 mg Spot-on solution for large cats
Active substances(s)	Praziquantel
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Loughrea Co. Galway Ireland
Legal basis of application	Generic application (Article 10(1) of Directive No 2001/83/EC)
Date of Authorisation	25/09/2020
Target species	Cats
Indication for use	For the treatment of tapeworm infections in cats weighing from 5 kg to 7.5 kg: *Dipylidium caninum* (immature and adult), *Taenia* spp (immature and adult) and *Echinococcus multilocularis*
ATCvet code	QP52AA01
Concerned Member States	DE, ES, FR, IT, NL, 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 60 mg of praziquantel and the excipients butylhydroxytoluene (E321) and N-methylpyrrolidone. The container/closure system consists of 1, 2, 3, 4 or 6 pipettes in individual foil sachets in a carton. The product is contained in a white pipette composed of a heat-formed shell composed of polypropylene/cyclic olefin copolymer/ethylene vinyl alcohol/polypropylene layers.

The choice of the formulation is justified. 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 praziquantel, an established active substance described in the European 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 has been provided.

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 substance 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)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, results of pharmacological and toxicological tests are not required. Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

III. SAFETY ASSESSMENT

User Safety
A user risk assessment was provided in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:

- The product can be irritating to the skin and eyes.
- Care should be taken to avoid the contents of the tube coming into contact with the skin, eyes and mouth, including hand-to-mouth and hand-to-eye contact.

- If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water.
- People with known hypersensitivity to Praziquantel should avoid contact with the veterinary medicinal product.
- In the event of skin or eye contact, seek medical advice if irritation persists and show the Doctor this package.
- Do not eat, drink or smoke during application.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
- Laboratory studies with the excipient N-methyl-2-pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects. Avoid direct contact with the product and application site.
- Do not stroke or groom animals until the area of application is dry (at least one hour after application).
- Wash hands thoroughly after use.
- Keep product in the outer carton until ready to use.
- Store away from food, drink and animal feeding stuffs.

Environmental Safety
The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines. The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required. The product is not expected to cause issues for the environment when used as recommended.

IV. CLINICAL ASSESSMENT

IV.I. Pre-Clinical Studies
As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Pharmacology

Pharmacodynamics
Praziquantel is active against all stages of development of intestinal tapeworms. The substance is very rapidly absorbed and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction, paralysis and death of the parasite.

Pharmacokinetics
Praziquantel is quickly absorbed through the skin after dermal application of the recommended dose of 8 mg/kg body weight of cats. Maximum serum concentrations are reached after approx. 3 hours at approx. 0.06 mg/l.
As studies in various animal species show, praziquantel is rapidly metabolized in the liver. The main metabolites of praziquantel are monohydroxyhexyl derivatives. Excretion is predominantly via the kidneys.

Tolerance in the Target Species
The tolerance profile of the product is essentially similar to that of the reference product. No additional data were required.

Resistance
There was no evidence of resistance in the target parasites in European isolates. No additional data were required.

IV.II. Clinical Documentation
As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required.
The efficacy claims for this product are equivalent to those of the reference product.
This was a generic application for Prazpronto 60mg Spot-on solution for large cats. The reference product is Droncit Spot-on 20 mg Solution, authorised in the UK since August 2000.
The product is indicated for the treatment of tapeworms of cats, and is effective against immature and adult forms of *Dipylidiumcaninum* and *Taenia* species in cats weighing from 5 to 7.5 kg. The product is also effective against *Echinococcus multilocularis*. The product should be administered at a minimum dose rate of 8 mg/kg bodyweight, which equates to 1 pipette of 1.5 ml for a large cat (> 5 – 7.5 kg) corresponding to a dose rate of 8 – 12 mg/kg bw. It is not be used in cats weighing less than 5 kg bodyweight.

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

None