Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bayer Praziquantel 50 mg Tablet

Date Created: 27th November 2014

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bayer Praziquantel 50 mg Tablets
Applicant	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA
Active substance	Praziquantel
ATC Vetcode	QP52AA01
Target species	Cat and Dog
Indication for use	For the treatment of adult tapeworms of cats and dogs. The tablets are effective against both immature and mature forms of adult tapeworms in both cats and dogs. The product is a highly effective treatment against all the common species of tapeworm infecting cats and dogs in the United Kingdom including *Echinococcus granulosus*, *Taenia ovis, Taenia pisiformis, Taenia multiceps, Taenia hydatigena, Taenia taeniaeformis,* and *Dipylidium caninum.* The product is also effective against *Echinococcus multilocularis.*

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Droncit 50 mg Tablets. The initial application for Droncit 50 mg Tablets was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. 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 of the product(s) is favourable.

MODULE 4

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)