Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Cat Wormer Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances	
Pyrantel Embonate	230.0 mg
Praziquantel	20.0 mg
Excipients	
Titanium dioxide (E171)	1.8 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.
White to yellowish, scored coated tablet.
The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of gastrointestinal roundworms and tapeworms:
Toxocara cati, Toxascaris leonina, Dipylidium caninum, Taenia taeniaeformis.

4.3 Contraindications

Do not use simultaneously with piperazine compounds.
Not intended for use in kittens less than 6 weeks of age.
Do not use during pregnancy.

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc is undertaken.

As a precautionary measure to prevent the establishment of *Echinococcus multilocularis* in the UK and Ireland, it is recommended that all cats entering the country be treated with praziquantel.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the medicinal product to animals

Do not remove tablets from strip packaging until required for use. Any part used tablets should be discarded.
In the interests of good hygiene, persons administering the tablets directly to a cat, or by adding them to the cat's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not to be used during pregnancy but may be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amounts to be administered and administration route

Dosage

The recommended dose rates are: 57.5 mg/kg pyrantel embonate and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg bodyweight.

2 kg bodyweight	½ tablet
4 kg bodyweight	1 tablet
6 kg bodyweight	1 ½ tablets

Administration and Duration of Treatment

Single oral administration. The tablet should be given directly to the animal, but if necessary can be disguised in food.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP52 AA51
Pharmacotherapeutic Group: Anthelmintics, *praziquantel combinations.*

The product contains two active ingredients:

1. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative

and

2. Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative

5.1 Pharmacodynamic properties

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow expulsion from the gastrointestinal (GI) system by peristalsis.

Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination product pyrantel is active against the following ascarids: *Toxocara cati* and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis*.

The product has also been shown to be efficacious in the control of hookworms, *Ancylostoma tubaeforme* and *A. braziliense* and the tapeworm *Joyeuxiella pasqualei*, none of which occur naturally in the UK or Ireland but may occasionally be found in imported animals. Since it contains praziquantel, the product is effective against *Echinococcus multilocularis,* which does not occur in the UK or Ireland but is becoming more common in some European countries.

5.2 Pharmacokinetic properties

Praziquantel is very rapidly absorbed into and distributed throughout the parasite.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Microcrystalline cellulose
Povidone
Magnesium stearate
Colloidal anhydrous silica
Hypromellose
Marcogol
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicianl product as packaged for sale: 5 years.
Any part used tablets should be discarded.

6.4 Special precautions for storage

Do not store above 25°C.
Do not remove tablets from strip packing until required for use.

6.5 Nature and composition of immediate packaging

Container material:	Aluminium foil blister or polyethylene-coated aluminium blister.
Closure:	Heat seal
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 20 or 100 tablets
	Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Ltd.
Animal Health Division
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10021/054/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th March 2009

Date of last renewal: 19th March 2014

10 DATE OF REVISION OF THE TEXT