SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Active substances:

Pyrantel embonate	230 mg
Praziquantel	20 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.
A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.
The tablets can be divided into 2 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

Roundworms: *Toxocara cati*, *Toxascaris leonina,*

Tapeworms: *Dipylidium caninum, Taenia taeniaeformis*, *Echinococcus multilocularis.*

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

Do not use in kittens less than 6 weeks of age.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

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 reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

4.5 Special precautions for use

i) Special precautions for use in animals

Not applicable.

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

In the interests of good hygiene, persons administering the tablets directly to the cat, or by adding them to the cat's food, should wash their hands afterwards.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

ii) Other precautions
Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

Target species: Cats

Very rare *(<1 animal / 10,000 animals treated, including isolated reports):*	*Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur.*

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Do not use 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 Amount(s) to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Dosage

The recommended dose is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg bodyweight.

Body weight	tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

Administration and duration of treatment

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

In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning.

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

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, praziquantel combinations.

ATC Vet Code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The product contains two active substances, as follows:

1. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative
and
2. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative.

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 gastro-intestinal (GI) system by peristalsis.
Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both in vitro and in vivo 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 vacuolization of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.
In this fixed combination, pyrantel is active against the following ascarids: *Toxocara cati*, and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis.*
Since it contains praziquantel, the product is effective against *Echinococcus multilocularis*.

5.2 Pharmacokinetic particulars

Praziquantel is rapidly absorbed, metabolised and distributed in the body. It is also believed to be excreted back into the intestinal lumen by the mucous membrane.
Following administration of the product to cats, peak plasma concentrations of praziquantel were achieved by approximately 2 hours.

Pyrantel is poorly absorbed so it is expected that a large proportion of the administered dose remains in the GIT where it exerts its therapeutic effect and it is excreted largely unchanged in the faeces.
Following administration of the product to cats, peak plasma concentrations of pyrantel were achieved by approximately 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:
Maize starch
Microcrystalline cellulose (E460)
Crospovidone
Magnesium stearate (E572)
Colloidal anhydrous silica,

Film coat
Grilled meat flavour
Opadry Complete Film Coating System 03F28415 White consisting of:
HPMC 2910 /Hypromellose (E464),
Macrogol/PEG 4000 (E1521),
Titanium Dioxide (E171).

6.2 Major Incompatibilities

Not Applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Discard unused half tablets.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.5 Nature and composition of immediate packaging

The product is presented in either:
Individual blisters made up of a PVC/PE/PCTFE white opaque copolymer and a 20µm heatseal lacquer/aluminium containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.
or
Individual blisters made up of 45µm PVC/aluminium/orientated polyamide and a 20µm heatseal lacquer/aluminium containing 2 or 8 tablets.

The blisters are packed into cartons containing either: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Medicines should not be disposed of via wastewater.

7 MARKETING AUTHORISATION HOLDER

C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 40162/5000

9. DATE OF FIRST AUTHORISATION

19 March 2015

10. DATE OF REVISION OF THE TEXT

December 2022

Approved 08 December 2022