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 (equivalent to 79.79mg of Pyrantel)
Praziquantel	20 mg

Excipient:

Qualitative composition of excipients and other constituents **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).*

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 two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each 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.*

3.3 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.

3.4 Special warnings

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.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infection such as fleas and mice.

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

3.5 Special precautions for safe use in the target species

Special precautions for use in animals

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

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 the label to the physician.

Special precautions for the protection of the environment:

Not Applicable

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.

3.6 Adverse events

Target species: Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (hypersalivation and/or vomiting) Neurological disorders (ataxia).

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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy but may be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

3.9 Administration routes and dosage

Oral use

To ensure 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

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 days intervals until 2-3 weeks after weaning. If signs of disease persist or appear, consult a veterinary surgeon.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

<To be completed nationally>

ES: <To be administered by a veterinary surgeon or under their direct responsibility>

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP52AA51

4.2 Pharmacodynamics 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*.

4.3 Pharmacokinetics 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not Applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the immediate packaging: use immediately.
Unused half tablets should be discarded.

5.3 Special precautions for storage

Keep the blister in outer carton.

5.4 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.

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

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
For UK only:
Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 40162/3000

8. DATE OF FIRST AUTHORISATION

19 March 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

<to be completed nationally>
Detailed information on this veterinary medicinal product is available in the Union Product Database.

Approved 08 December 2022