LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 AND 44 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats (UK)

Propancat 230/20mg Flavoured Film coated tablets for cats (ES, IT)

Pyrantel embonate, Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For oral administration.

1 tablet per 4 kg bodyweight.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Discard unused half tablets.

11. SPECIAL STORAGE CONDITIONS

Keep blister in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<to be completed nationally>

16. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/4009

17. MANUFACTURER'S BATCH NUMBER

BN{number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 48 TABLETS, AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats (UK)

Propancat 230/20mg Flavoured Film coated tablets for cats (ES, IT)

Pyrantel embonate, Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cats

6. INDICATION(S)

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.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: 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

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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Discard unused half tablets.

11. SPECIAL STORAGE CONDITIONS

Keep blister in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<to be completed nationally>

16. MARKETING AUTHORISATION NUMBER(S)

<to be completed nationally>

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats (UK)

Propancat 230/20mg Flavoured Film coated tablets for cats (ES, IT)

Pyrantel embonate, Praziquantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<to be completed nationally>

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats (UK)

Propancat 230/20mg Flavoured Film **coated tablets for cats (ES, IT)**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
UK:
C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

ES, IT:
Fatro
Via Emilia 285
40064 Ozzano Emilia (Bologna)
ITALY

Manufacturer for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milaxyn 230/20mg Flavoured Film Coated Tablets for Cats (UK)

Propancat 230/20mg Flavoured Film coated tablets for cats (ES, IT)

Pyrantel embonate, Praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each film coated tablet contains:

Active substances:
Pyrantel embonate *230 mg*
Praziquantel *20 mg*

Excipients, q.s.

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. INDICATION(S)

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.*

5. CONTRAINDICATIONS

Do not use simultaneously with products containing piperazine.

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.

6. ADVERSE REACTIONS

Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur very rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep blister in outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Discard unused half tablets..

12. SPECIAL WARNING(S)

Special precautions for use in animals :

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

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

been observed.

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

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.

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

In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.

In the interests of good hygiene, persons administering the tablets directly to a cat or adding them to the cat's food should wash their hands afterwards.

For animal treatment only.

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.

Pregnancy, lactation or lay:

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

Overdose:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon/pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2015

15. OTHER INFORMATION

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.

NFA-VPS

Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility