A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin 230 mg/20 mg film-coated tablets for cats

Pyrantel embonate/praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
Pyrantel embonate 230 mg (equivalent to 80 mg pyrantel)
Praziquantel 20 mg

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PACKAGE SIZE

2 tablets
4 tablets
10 tablets
30 tablets
50 tablets
100 tablets

5. TARGET SPECIES

Cats.

6. INDICATION(S)

*****Only for those countries where the product is available without prescription :*****
For the treatment of mixed infestations with roundworms, hookworms and tapeworms

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Oral use.
1 tablet per 4 kg bodyweight.

*****Only for those countries where the product is available without prescription :*****
Dosage:
5 mg praziquantel and 20 mg pyrantel base (57.5 mg pyrantel embonate) per kg of body weight.

body weight	Tablets
1.0 - 2.0 kg	1/2
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 1/2
6.1 - 8.0 kg	2

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of halved tablets after first opening the immediate packaging: 1 month.

11. SPECIAL STORAGE CONDITIONS

Store unused parts of the halved tablets below 25°C. Each time an unused part-tablet is stored until next use, it should be returned to the open blister pocket and kept in a safe place out of the sight and reach of children.

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.

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

KRKA d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4116

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin 230 mg/20 mg film-coated tablets for cats
Pyrantel embonate/praziquantel

*****Only in case of multilingual blister:*****
Pyrantel embonate/praziquantel
Pyranteli embonas/praziquantelum

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Anthelmin 230 mg/20 mg film-coated tablets for cats

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

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin 230 mg/20 mg film-coated tablets for cats
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 (equivalent to 80 mg pyrantel)
Praziquantel 20 mg

White to almost white, biconvex, oval film-coated tablet, scored on one side. The tablet can be divided into halves.

4. INDICATION(S)

For the treatment of mixed infestations with roundworms, hookworms and tapeworms in cats, caused by:
- Roundworms: *Toxocara cati* (adults)
- Hookworms: *Ancylostoma tubaeforme* (adults)*, Ancylostoma braziliense* (adults)
- Tapeworms*: Echinococcus multilocularis, Dipylidium caninum, Hydatigera (Taenia) taeniaeformis, Mesocestoides* spp.*, Joyeuxiella pasqualei.*

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Please see section 12.

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 in very rare cases.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cats.

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

Single oral administration.

Dosage:
5 mg praziquantel and 20 mg pyrantel base (57.5 mg pyrantel embonate) per kg of body weight. This corresponds to 1 tablet per 4 kg of body weight.

body weight	Tablets
1.0 - 2.0 kg	1/2
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 1/2
6.1 - 8.0 kg	2

Kittens weighing less than 1 kg should not be treated with the product, because correct dosing of such cats may not be feasible.

Route of administration:
Oral use.
The tablets are to be given directly into the mouth but can be administered in a small amount of food, if necessary.

9. ADVICE ON CORRECT ADMINISTRATION

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

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.
If signs of disease persist or appear, consult a veterinary surgeon.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store unused parts of the halved tablets below 25 °C.
Each time an unused part-tablet is stored until next use, it should be returned to the open blister pocket and kept in a safe place out of the sight and reach of children.
Shelf life of halved tablets after first opening the immediate packaging: 1 month.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Tapeworm infestation occurs in cats at the earliest in the third week of life.
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.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, this may be due to underestimation of body weight or misadministration
of the product.

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 interest 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.
Unused part-tablets should be returned to the open blister pocket and kept in a safe place out of the sight and reach of children.

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.

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy. The product should not be used during pregnancy but may be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine compounds, because the specific activities of piperazine (neuromuscular paralysis of the parasites) can inhibit the efficacy of pyrantel (spastic paralysis of the parasites).

Overdose (symptoms, emergency procedures, antidotes):
Symptoms of overdoses do not occur less than 5 times the recommended dose. The first expected sign of intoxication is vomiting.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

Pack sizes:
Box with 1 blister of 2 tablets.
Box with 2 blisters of 2 tablets.
Box with 1 blister of 10 tablets.
Box with 3 blisters of 10 tablets.
Box with 5 blisters of 10 tablets.
Box with 10 blisters of 10 tablets.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 01 April 2022