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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

2 x 1 tablets
4 x 1 tablets
10 x 1 tablets
30 x 1 tablets
50 x 1 tablets
100 x 1 tablets

4. TARGET SPECIES

CATS

5. INDICATION(S)

For the treatment of mixed infestations with roundworms, hookworms and tapeworms

6. ROUTES OF ADMINISTRATION

Oral use.
1 tablet per 4 kg bodyweight.

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

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton.
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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 01656/5054

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

NFA-VPS

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anthelmin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Pyrantel embonate 230 mg
Praziquantel 20 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

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.

3. TARGET SPECIES

Cats.

4. INDICATIONS FOR USE

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 6.

6. 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 veterinary medicinal 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.
Do not use during pregnancy.

Lactation:
Can 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.

7. ADVERSE REACTIONS

Cats:

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

*Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {https://www.gov.uk/report-veterinary-medicine-problem}.

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

Oral use. Single 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 veterinary medicinal product, because correct dosing of such cats may not be feasible.

Route of administration:
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 veterinary medicinal 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 PRECAUTIONS FOR DISPOSAL

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.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

2 x 1, 4 x 1, 10 x 1, 30 x 1, 50 x 1 or 100 x 1 tablet in perforated unit dose blisters, in a box.
Not all pack sizes may be marketed.

Vm 01656/5054

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia
Tel: +44 2071 646156

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

Approved 20 October 2023