# ANNEX III

# LABELLING AND PACKAGE LEAFLET

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{BOX}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Roundworm and Tapeworm Wormer 230 mg/20 mg film-coated tablets for cats
Pyrantel embonate/praziquantel

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
**Active substances:**

| | |
|---|---|
| Pyrantel embonate | 230 mg (equivalent to 80 mg pyrantel) |
| Praziquantel | 20 mg |

## 3. PHARMACEUTICAL FORM

Film-coated tablet

## 4. PACKAGE SIZE

2 tablets

## 5. TARGET SPECIES

Cats.

## 6. INDICATION(S)

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 body weight.

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

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

Any unused tablet halves should be discarded or returned to the blister, and the blister placed back in the carton.

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.

## 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: ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

AVM-GSL

## 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

Vm 01656/3003

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{BLISTER}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Roundworm and Tapeworm Wormer 230 mg/20 mg film-coated tablets for cats
Pyrantel embonate/praziquantel

## 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.

# PACKAGE LEAFLET FOR:

## Krka Roundworm and Tapeworm Wormer 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
Šmarkeška 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

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka Roundworm and Tapeworm Wormer 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:

- adult stages of roundworms: *Toxocara cati (syn. mystax)*
- adult stages of hookworms: *Ancylostoma tubaeforme, Ancylostoma braziliense*
- tapeworms*: Echinococcus multilocularis, Dipylidium caninum, Hydatigera (Taenia) taeniaeformis, Mesocestoides spp., Joyeuxiella pasqualei.*

Roundworms and tapeworms are parasites that live in the gut. If left untreated they can cause your cat to become unwell. Treating your cat regularly will reduced the risk of other animals and humans being exposed to worm infections.

## 5. CONTRAINDICATIONS

Do not use simultaneously with products containing piperazine.

Do not use simultaneously with other deworming products without veterinary advice.
Do not use in kittens less than 6 weeks of age,
Do not use in animals known to be allergic to the active substances (pyrantel embonate and praziquantel) or to any of the other ingredients (excipients).
Do not use during pregnancy.

## 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 extremely 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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF 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. To ensure administration of a correct dose, body weight should be determined as accurately as possible.

| 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.
*Duration of use*:
Single treatment

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 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.
Any unused tablet halves should be safely discarded or returned to the open blister space, and returned to the outer carton.
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.

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

from the relevant competent authority. Seek advice from your veterinary surgeon if your pet may have visited a region where echinococcosis is found.

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.

Incompatibilities:
Not applicable.

## 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. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

## 15. OTHER INFORMATION

Box with 1 blister of 2 tablets.

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

For Animal Treatment Only

AVM-GSL

Local representative:
KRKA UK Ltd, United Kingdom, Tel: 02071 646 156, Email: info.uk@krka.biz

Approved 16 January 2024