PACKAGE LEAFLET FOR:

Anthelmin 230 mg/20 mg film-coated tablets for cats (CY, GR, PL)
Dehinel 230 mg/20 mg film-coated tablets for cats (DE, IT)
Anthelmin film-coated tablets for cats (FR)

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 (CY, GR, PL)
Dehinel 230 mg/20 mg film-coated tablets for cats (DE, IT)
Anthelmin film-coated tablets for cats (FR)
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 and tapeworms in cats, caused by:
- adult stages of ascarids: *Toxocara cati (syn. mystax)*
- adult stages of hookworms: *Ancylostoma tubaeforme, Ancylostoma braziliense*
- tapeworms*: Echinococcus multilocularis, Dipylidium caninum, Hydatigera (Taenia) taeniaeformis, Mesocestoides spp., Joyeuxiella pasqualei.*

5. CONTRAINDICATIONS

Do not use in cases of known 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.

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.

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.
Treatment may be repeated in 3-month intervals to control roundworms. (CMS, where OTC distribution category applies).

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

It is recommended that all the animals living in the same household should be treated at the same time.
In the case of suspected lack of efficacy or when the product is repeatedly used over a longer period it is recommended to contact a veterinarian who may order appropriate laboratory tests and/or administer another deworming product with a different mode of action. (CMS, where OTC distribution category applies).

Special precautions for use in 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. (CMS, where OTC distribution category applies).

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.

Other precautions:
Echinococcosis represents a hazard for humans. In case of Echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed. Therefore, experts (e.g. veterinarians) or institutes of parasitology should be consulted.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box with 1 blister of 2 tablets.
Box with 2 blisters of 2 tablets.
Box with 1 blister 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.