ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dehinel 230 mg/20 mg film-coated tablets for cats (BG, CZ, EE, ES, HR, HU, LT, LV, NL, PL, PT, RO, SI, SK)
Anthelmin 230 mg/20 mg film-coated tablets for cats (AT, BE, DE, IE, IT, UK)
Anthelmin vet 230 mg/20 mg film-coated tablets for cats (FI)
Dehinel film-coated tablets for cats (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:
Active substances:

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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.*

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.
Please see section 4.7 and section 4.8.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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. 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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).

4.9 Amounts to be administered and administration route

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

Note:
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Symptoms of overdoses do not occur less than 5 times the recommended dose. The first expected sign of intoxication is vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, quinoline derivatives and related substances, praziquantel, combinations.
ATCvet code: QP52AA51

5.1 Pharmacodynamic properties

The product is a roundworm and tapeworm anthelmintic containing as active constituents the pyrazinoisoquinolinone derivative praziquantel and the tetrahydropyrimidine derivative pyrantel (as embonate salt)

In this fixed combination praziquantel serves as a tapeworm agent whose action spectrum covers cestode species in cats, in particular *Hydatigera (Taenia) taeniaeformis, Joyeuxiella pasqualei., Dipylidium caninum, Mesocestoides spp.* and *Echinococcus multilocularis*. Praziquantel acts against all stages of these parasites occurring in the cat intestine.

Pyrantel is the roundworm-specific component and has a good activity against nematodes occurring in cats, in particular *Toxocara cati (syn. mystax),* and *Ancylostoma tubaeformae and Ancylostoma braziliense*. Pyrantel acts as a cholinergic agonist similarly to nicotine, and causes spastic paralysis of the nematodes by a depolarising neuromuscular blockade.

Praziquantel is absorbed very rapidly through the parasite's surface and is distributed evenly inside the parasite. Both in vitro and in vivo severe damage to the parasite integument sets in very quickly, resulting in contraction and paralysis of the parasites. The basis for the rapid onset of action is above all the praziquantel-induced change in the permeability of the parasite membrane to Ca^{++}, which leads to a dysregulation of the parasite metabolism.

5.2 Pharmacokinetic particulars

Praziquantel is rapidly absorbed following oral administration. Maximum serum levels are achieved within 2 hours. Praziquantel is widely distributed and is rapidly metabolised in the liver. In addition to other metabolites, the main metabolite occurring in each case is the 4-hydroxycyclohexyl derivative of praziquantel. Praziquantel is completely eliminated within 48 hours in the form of its metabolites - between 40 and 71 % in the urine and, in bile, between 13 and 30 % in the faeces.

The embonate salt of pyrantel is poorly absorbed from the gastrointestinal tract..

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Povidone K25
Cellulose, microcrystalline (E460)
Silica, colloidal anhydrous
Magnesium stearate (E572)
Hypromellose
Macrogol 4000
Titanium dioxide (E171)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life of halved tablets after first opening the immediate packaging: 1 month.

6.4. Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

Blister packs consisting of cold formed OPA/Aluminium/PVC foil and aluminium foil in a box.
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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.