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, PL, PT, RO, SI, SK)
Anthelmin 230 mg/20 mg film-coated tablets for cats (AT, BE, DE, IE, IT, UK (NI))
Anthelmin vet 230 mg/20 mg film-coated tablets for cats (FI)
Dehinel film-coated tablets for cats (FR)
Wormmiddel All-in-one Kat 230 mg/20 mg film-coated tablets for cats (NL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Povidone K25
Cellulose, microcrystalline (E460)
Silica, colloidal anhydrous
Magnesium stearate (E572)
Hypromellose
Macrogol 4000
Titanium dioxide (E171)

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

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For the treatment of mixed infestations with roundworms, hookworms and tapeworms in cats, caused by:

- Ascarids (roundworms): *Toxocara cati* (adults)
- Hookworms: *Ancylostoma tubaeforme* (adults)*, Ancylostoma braziliense* (adults)
- Cestodes (tapeworms)*: Echinococcus multilocularis, Dipylidium caninum, Hydatigera (Taenia) taeniaeformis, Mesocestoides* spp.*, Joyeuxiella pasqualei.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Please see section 3.7 and section 3.8.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species

Not applicable.

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.

Special precautions for the protection of the environment

Not applicable.

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.

3.6 Adverse events

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. ataxia)*

*Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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).

3.9 Administration routes and dosage

Oral use. Single administration.

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

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.

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 veterinary medicinal product at 14 day intervals until 2-3 weeks after weaning.
If signs of disease persist or appear, consult a veterinary surgeon.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51

4.2 Pharmacodynamics

The veterinary medicinal 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,* 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.

4.3 Pharmacokinetics

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..

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 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.

5.4 Nature and composition of immediate packaging

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

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. (AT, CZ (packaging for 30, 50, 100 tbl), DE, ES, FI (packaging for 30, 50, 100 tbl), FR (packaging for 30, 50, 100 tbl))

Veterinary medicinal product not subject to prescription.(BE, BG, CZ (packaging for 2, 4, 10 tbl), EE, FI (packaging for 2, 4, 10 tbl), FR (packaging for 2, 4, 10 tbl, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

For memory stickers:
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. PACKAGE SIZE

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

4. TARGET SPECIES

CATS

5. INDICATIONS

For products not subject to veterinary prescription :
For the treatment of mixed infestations with roundworms, hookworms and tapeworms

6. ROUTES OF ADMINISTRATION

Oral use.
1 tablet per 4 kg bodyweight.

For products not subject to veterinary 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

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dehinel (BG, CZ, EE, ES, HR, HU, LT, LV, PL, PT, RO, SI, SK, FR)
Anthelmin (AT, BE, DE, IE, IT, UK(NI))
Anthelmin vet (FI)
Wormmiddel All-in-one Kat (NL)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

230 mg/20 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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, PL, PT, RO, SI, SK)
Anthelmin 230 mg/20 mg film-coated tablets for cats (AT, BE, DE, IE, IT, UK (NI))
Anthelmin vet 230 mg/20 mg film-coated tablets for cats (FI)
Dehinel film-coated tablets for cats (FR)
Wormmiddel All-in-one Kat 230 mg/20 mg film-coated tablets for cats (NL)

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 warnings

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

Major incompatibilities:
Not applicable.

7. Adverse events

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes 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 periods

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. (AT, CZ (packaging for 30, 50, 100 tbl), DE, ES, FI (packaging for 30, 50, 100 tbl), FR (packaging for 30, 50, 100 tbl))

Veterinary medicinal product not subject to prescription (BE, BG, CZ (packaging for 2, 4, 10 tbl), EE, FI (packaging for 2, 4, 10 tbl), FR (packaging for 2, 4, 10 tbl, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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
Telephone number, if applicable

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

Local representatives and contact details to report suspected adverse reactions:

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