[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal 230 mg/20 mg film-coated tablets for cats [DE] [ES]
Drontal chat [FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Pyrantel embonate (equivalent to 80 mg pyrantel)	230.0 mg
Praziquantel	20.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Core:
Maize starch
Cellulose, microcrystalline
Povidone K25
Magnesium stearate
Silica, colloidal anhydrous
Coating:
Calcium carbonate
Hypromellose
Isomalt
Triglycerides, medium-chain

White-yellowish divisible tablets with a score line on both sides.

3. CLINICAL INFORMATION

3.1 Target species

Cat.

3.2 Indications for use for each 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

Since tapeworm infestation occurs in cats at the earliest in the third week of life, treatment with the veterinary medicinal product is not indicated until after the third week.

3.3 Contraindications

Until sufficient studies have been performed with the combination, the veterinary medicinal product should not be used during pregnancy.

3.4 Special warnings

Parasite resistance to any particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

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 the interests 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. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Since it contains praziquantel, the product is effective against *Echinococcus* spp. which do not occur in all EU member states but are becoming more common in some. 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.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorder[1,2] (e.g. hypersalivation, vomiting, diarrhoea) Neurological disorder[2] (e.g. ataxia)

[1] Mild
[2] 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 and lactation:

Until sufficient studies have been performed with the combination, do not use during pregnancy (see section 3.3).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Dosage:

To ensure a correct dosage, body weight should be determined as accurately as possible.

1 x 5 mg praziquantel and 57,5 mg pyrantel embonate (20 mg pyrantel base) per kg of body weight. This corresponds to 1 tablet per 4 kg of body weight.

Body weight	Tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

Kittens weighing less than 1 kg should not be treated with the veterinary medicinal product.

Route of administration:

Oral use.

The tablets are to be given directly or covered in meat or sausage. No dietetic measures are necessary.

Duration of use:

Single treatment.

Note:
In ascarid infestation, especially in pups, 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.

If Echinococcosis has been diagnosed a special strategy regarding treatment, check-ups and personal protection should be embarked on. Therefore, it is recommended to consult specialised veterinarians or institutes for parasitology.

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 all important 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 efficacy against all relevant 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.

4.3 Pharmacokinetics

Praziquantel is absorbed very rapidly and almost completely in the stomach and small intestine following oral administration to all species investigated. Maximum serum levels are already reached within 0.3 to 2 hours. Praziquantel is very rapidly distributed into all organs. The elimination half-lives of ^{14}C-praziquantel and its metabolites are between 2 and 3 hours in all investigated species. Praziquantel 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, via the bile, between 13 and 30 % in the faeces.

The embonate salt of pyrantel is poorly absorbed from the gastrointestinal tract in all investigated species.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

2, 4, 6, 8, 20, 24, 96, 100 or 144 tablets in OPA/Alu/HDPE-PE/Alu-blisters in a cardboard box.

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

Vetoquinol S.A.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. [DE],[ES]
Veterinary medicinal product subject to prescription except for some pack sizes. [FR]

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Folding box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal 230 mg/20 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Pyrantel embonate (equivalent to 80 mg pyrantel)	230.0 mg
Praziquantel	20.0 mg

3. PACKAGE SIZE

2 tablets.
4 tablets.
6 tablets.
8 tablets.
20 tablets.
24 tablets.
96 tablets.
100 tablets.
144 tablets.

4. TARGET SPECIES

Cat.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet = 4 kg (with tablet pictogram/graphic)

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pyrantel embonate (equivalent to 80 mg pyrantel)	230.0 mg
Praziquantel	20.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Drontal 230 mg/20 mg film-coated tablets

2. Composition

Each tablet contains:

Active substances:

Pyrantel embonate (equivalent to 80 mg pyrantel)	230.0 mg
Praziquantel	20.0 mg

White-yellowish divisible tablets with a score line on both sides.

3. Target species

Cat.

4. Indications for use

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*

Since tapeworm infestation occurs in cats at the earliest in the third week of life, treatment with the veterinary medicinal product is not indicated until after the third week.

5. Contraindications

Until sufficient studies have been performed with the combination, the veterinary medicinal product should not be used during pregnancy.

6. Special warnings

Special warnings:

Parasite resistance to any particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the interests 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.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

Since it contains praziquantel, the product is effective against *Echinococcus* spp. which do not occur in all EU member states but are becoming more common in some. 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.

Pregnancy and lactation:

Until sufficient studies have been performed with the combination, do not use during pregnancy (see Contraindications).

Overdose:

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

7. Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Digestive tract disorder[1,2] (hypersalivation, vomiting, diarrhoea) Neurological disorder[2] (ataxia)

[1] Mild
[2] Transient

Reporting adverse events is important. It allows continuous safety monitoring of a 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 its local representative> using the contact details at the end of this leaflet, or via your national reporting system: *[To be completed nationally]*

8. Dosage for each species, routes and method of administration

Dosage:

1 x 5 mg praziquantel and 57,5 mg pyrantel embonate (20 mg pyrantel base) per kg of body weight. This corresponds to 1 tablet per 4 kg of body weight.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Body weight	Tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

Kittens weighing less than 1 kg should not be treated with the veterinary medicinal product.

Route of administration:

Oral use.

Duration of use:

Single treatment.

Note:
In ascarid infestation, especially in pups, 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.

If Echinococcosis has been diagnosed a special strategy regarding treatment, check-ups and personal protection should be embarked on. Therefore, it is recommended to consult specialised veterinarians or institutes for parasitology.

9. Advice on correct administration

The tablets are to be given directly or covered in meat or sausage. No dietetic measures are necessary.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister 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. [DE],[ES]
Veterinary medicinal product subject to prescription except for some pack sizes. [FR]

14. Marketing authorisation numbers and pack sizes

2, 4, 6, 8, 20, 24, 96, 100 or 144 tablets in OPA/Alu/HDPE-PE/Alu-blisters in a cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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 events>:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

<Local representatives and contact details to report suspected adverse events:>

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