[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Austria Cyprus Czech Republic Portugal Slovakia Hungary Slovenia Germany Finland	Dolpac large dogs tablets
France Luxembourg	Dolpac 25 comprimé
Poland Spain	Dolpac large dogs tablets for 20-75 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Oxantel	500.70 mg (equivalent to 1397.5 mg of oxantel embonate)
Pyrantel	124.85 mg (equivalent to 360 mg of pyrantel embonate)
Praziquantel	125.00 mg

Excipients:

Qualitative composition of excipients and other constituents
Dextrates
Povidone K30
Sodium Lauryl sulphate
Bacon flavour
Crospovidone
Sodium stearyl fumarate

Pale yellow to yellow oblong tablet with breaking line.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For curative treatment of dogs harbouring mixed parasitic infestations with the following adult stages of nematode and cestode species:

Nematodes:

Toxocara canis
Toxascaris leonina
Ancylostoma caninum
Uncinaria stenocephala
Trichuris vulpis

Cestodes:

Dipylidium caninum
Taenia spp
Echinococcus multilocularis
Echinococcus granulosus

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

See section 3.8 "*Interaction with other medicinal products and other forms of interaction*".

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 of the common tapeworms – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts (fleas) is undertaken.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Roundworm and Hookworm infection:

In some animals, *Ancylostoma caninum* and *Toxocara canis* may not be totally eradicated by the treatment, resulting in a continued risk of egg shedding into the environment. Follow-up examinations of the faeces are advisable and according to the results of these examinations, treatment with a nematodicidal veterinary medicinal product may be carried out if necessary.

The veterinary medicinal product is not recommended for use in pups younger than two months old or weighing less than 1 kg.

In debilitated or heavily infested animals, use only according to the benefit-risk assessment by the responsible veterinarian.

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

Some constituents of this veterinary medicinal product may cause allergic reactions or skin irritation.

Avoid contact with the skin.

People with known hypersensitivity to the active substances or to any of the excipients should avoid contact with the veterinary medicinal product.

Wash hands after use.

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.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Anorexia[1]
Rare (1 to 10 animals / 10 000 animals treated):	Vomiting, diarrhoea

[1] *Common side effect of praziquantel-containing medicines*

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with levamisole, piperazine or choline esterase inhibitors.

3.9 Administration routes and dosage

Oral use.

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

The recommended dose rate is 20 mg oxantel / 5 mg pyrantel / 5 mg praziquantel per kg bodyweight, ie one tablet per 25 kg bodyweight in a single intake.

Administer the required number of tablets, according to bodyweight, orally, in a single administration. Preferably, dogs should be fasted prior to treatment. Food may be given one hour or more after treatment.

Weight of dog	Number of tablets
From 10.1 to 12.5 kg	½
From 12.6 to 25 kg	1
From 25.1 to 50 kg	2
From 50.1 to 75 kg	3

The tablet can be divided into halves.

Dogs kept together or in kennels should be treated at the same time.

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

Administration of the veterinary medicinal product to healthy dogs at 5 times the recommended dosage for 6 consecutive weeks had no adverse consequences.

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 contains three active ingredients, pyrantel embonate, oxantel embonate and praziquantel. The spectrum of activity of the veterinary medicinal product is wide, directed towards gastro-intestinal roundworms (ascaris, whipworm and hookworms) and tapeworms.

Pyrantel has a paralysing effect on roundworm muscles, by activating acetylcholine receptors. Its activity is more particularly directed against *Toxocara canis, Toxascaris leonina, Uncinaria stenocephala* and *Ancylostoma caninum*. Its activity against *Trichuris vulpis* is negligible.

Oxantel is an m-oxyphenolic derivate of pyrantel, that has been developed for its activity against whipworms.

Praziquantel leads to muscular contractions, paralysis and altered parasite tegument integrity. It is active against adults and larval stages of dog tapeworms, *Echinococcus, Taenia* and *Dipylidium*.

4.3 Pharmacokinetics

After oral administration, the absorption of oxantel embonate is negligible. Pyrantel is quickly absorbed but in small quantities (T_{max} = 1.38 h, C_{max} = 0.048 µg/ml) and is very quickly eliminated. Praziquantel is quickly absorbed (T_{max} = 1.28 h, C_{max} = 0.4 µg/ml) and eliminated (elimination half-life 1.5 h).

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.

Discard any unused half tablet.

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

Container material: Polyamide-aluminium-PVC/aluminium blister or polychlorotrifluoroethylene-PVC/aluminium blister strip of 3 tablets.

Container sizes: Cardboard box with 1 strip of 3 tablets.
Cardboard box with 6 strips of 3 tablets.
Cardboard box with 10 strips of 3 tablets.
Cardboard box with 20 strips of 3 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

7. MARKETING AUTHORISATION NUMBER(S)

8. 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 [AT][CY][CZ][PT][SK][HU][SI][DE][FR][PL][ES]
Veterinary medicinal product not subject to prescription [LU]
Veterinary medicinal product subject to prescription except for some pack sizes [FI]

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

CARDBOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolpac large dogs tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Oxantel	500.70 mg (equivalent to 1397.5 mg of oxantel embonate)
Pyrantel	124.85 mg (equivalent to 360 mg of pyrantel embonate)
Praziquantel	125.00 mg

(EN/Latin)

3. PACKAGE SIZE

3 tablets.
18 tablets.
30 tablets.
60 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

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

[To be completed nationally]

14. MARKETING AUTHORISATION NUMBERS

[To be completed nationally]

15. BATCH NUMBER

Lot {number}

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolpac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Oxantel 500.70 mg
Pyrantel 124.85 mg
Praziquantel 125.00 mg
(EN/Latin)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dolpac large dogs tablets

2. Composition

Each tablet contains:

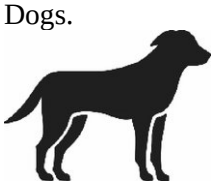
Active substances:

Oxantel	500.70 mg (equivalent to 1397.5 mg of oxantel embonate)
Pyrantel	124.85 mg (equivalent to 360 mg of pyrantel embonate)
Praziquantel	125.00 mg

Pale yellow to yellow oblong tablet with breaking line.

3. Target species

Dogs.



4. Indications for use

For curative treatment of dogs harbouring mixed parasitic infestations with the following adult stages of nematode and cestode species:

Nematodes:

Toxocara canis
Toxascaris leonina
Ancylostoma caninum
Uncinaria stenocephala
Trichuris vulpis

Cestodes:

Dipylidium caninum
Taenia spp
Echinococcus multilocularis
Echinococcus granulosus

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

See subsection "*Interaction with other medicinal products and other forms of interaction*".

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 of the common tapeworms – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts (fleas) is undertaken.

Special precautions for safe use in the target species:

Roundworm and Hookworm infection:

In some animals, *Ancylostoma caninum* and *Toxocara canis* may not be totally eradicated by the treatment, resulting in a continued risk of egg shedding into the environment. Follow-up examinations of the faeces are advisable and according to the results of these examinations, treatment with a nematodicidal veterinary medicinal product may be carried out if necessary.

The veterinary medicinal product is not recommended for use in pups younger than two months old or weighing less than 1 kg.

In debilitated or heavily infested animals, use only according to the benefit-risk assessment by the responsible veterinarian.

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

Some constituents of this veterinary medicinal product may cause allergic reactions or skin irritation.

Avoid contact with the skin.

People with known hypersensitivity to the active substances or to any of the excipients should avoid contact with the veterinary medicinal product.

Wash hands after use.

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

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

The use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with levamisole, piperazine or choline esterase inhibitors.

Overdose:

Administration of the veterinary medicinal product to healthy dogs at 5 times the recommended dosage for 6 consecutive weeks had no adverse consequences.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Anorexia[1]
Rare (1 to 10 animals / 10 000 animals treated):
Vomiting, diarrhoea

[1] *Common side effect of praziquantel-containing medicines*

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: {national system details}

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

Oral use.

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

The recommended dose rate is 20 mg oxantel / 5 mg pyrantel / 5 mg praziquantel per kg bodyweight, ie one tablet per 25 kg bodyweight in a single intake.

Administer the required number of tablets, according to bodyweight, orally, in a single administration. Preferably, dogs should be fasted prior to treatment. Food may be given one hour or more after treatment.

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From 12.6 to 25 kg	1
From 25.1 to 50 kg	2
From 50.1 to 75 kg	3

The tablet can be divided into halves.

Dogs kept together or in kennels should be treated at the same time.

9. Advice on correct administration

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 or the blister after Exp. The expiry date refers to the last day of that month.

Discard any unused half tablet.

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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription [AT][CY][CZ][PT][SK][HU][SI][DE][FR][PL][ES]
Veterinary medicinal product not subject to prescription [LU]
Veterinary medicinal product subject to prescription except for some pack sizes [FI]

14. Marketing authorisation numbers and pack sizes

[To be completed nationally]

Container sizes:
Cardboard box with 1 strip of 3 tablets.
Cardboard box with 6 strips of 3 tablets.
Cardboard box with 10 strips of 3 tablets.
Cardboard box with 20 strips of 3 tablets.

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> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

[To be completed nationally]

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

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

[To be completed nationally]

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

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