

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the veterinary medicinal product

DOLPAC 10 VETERINARY

DOLPAC 25 VETERINARY

### 2. Qualitative and quantitative composition

Each tablet contains:

#### **Active substances:**

#### DOLPAC 10 VETERINARY:

Oxantel (as embonate) 200.28 mg

Pyrantel (as embonate) 49.94 mg

Praziquantel 50.00 mg

#### DOLPAC 25 VETERINARY:

Oxantel (as embonate) 500.70 mg

Pyrantel (as embonate) 124.85 mg

Praziquantel 125.00 mg

#### **Excipients:**

#### **Qualitative composition of excipients and other constituents**

Dextrates

Crospovidone

Sodium stearyl fumarate

Povidone K30

Lauryl sodium sulphate

Bacon flavour

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 nematodes and cestode species :

Nematodes :

*toxocara canis*, *toxocaris leonine*, *ancylostoma caninum*, *uncinaria stenocephala*, *trichuris vulpis*.

Cestodes :

*Dipylidium caninum* *taenia* spp.

#### **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 nematocidal 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 <sup>1</sup>
Rare (1 to 10 animals / 10 000 animals treated):	Vomiting, diarrhoea

<sup>1</sup> *Common side effect of praziquantel-containing medicines*

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

**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**

DOLPAC 10 VETERINARY

The recommended dose is 20 mg of oxantel/5 mg pyrantel/5 mg praziquantel per kg bodyweight, i.e. one tablet per 10 kg bodyweight in a single dose, orally.

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

Weight of dog	Number of tablets
From 3.1 - 5 kg	½
From 5.1 - 10 kg	1
From 10.1 - 20 kg	2
From 20.1 - 30 kg	3

Tablets can be divided into two equal halves.

Dogs living together or in kennels should be treated simultaneously.

#### DOLPAC 25 VETERINARY

The recommended dose is 20 mg of oxantel/5 mg pyrantel/5 mg praziquantel per kg bodyweight, i.e. one tablet per 25 kg bodyweight in a single dose, orally.

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

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

Tablets can be divided into two equal halves.

Dogs living together or in kennels should be treated simultaneously.

#### **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**

The expiry date of the product is indicated on the packaging materials. Discard any unused half tablets.

### **5.3 Special precautions for storage**

Store below 25°C

### **5.4 Nature and composition of immediate packaging**

Polychlorotrifluoroethylene-PVC/aluminium blister

The tablets are packed in blisters.

Each package contains:

Dolpac 10 Veterinary: 3, 6, 18, 30 or 60 tablets

Dolpac 25 Veterinary: 3,18,30,60 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**

Eliezer Linevitz Ltd., Kanot Industrial Area, Adom 6 St., P.O.B 7006, Israel

**7. MARKETING AUTHORISATION NUMBER(S)**

DOLPAC 10 VETERINARY: 142-76-92430

DOLPAC 25 VETERINARY: 142-77-92433

**8. MANUFACTURER**

Vetoquinol S.A.,  
Magny-Vernois  
70200 Lure, France

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