SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

DOLPAC 10 VETERINARY

DOLPAC 25 VETERINARY

2. Qualitative and quantitative composition

DOLPAC 10 VETERINARY:

Oxantel ……..(as embonate) (equivalent to 559 mg of oxantel embonate)	200.28 mg
Pyrantel……..(as embonate) (equivalent to 144 mg of oxantel embonate)	49.94 mg
Praziquantel ……..	50.00 mg

Excipient QS for one pre-scored 950-mg tablet

For the full list of excipients, see 'List of excipients' section.

DOLPAC 25 VETERINARY:

Oxantel ……..(as embonate)

(equivalent to 1395,5 mg of oxantel embonate) 500.70 mg

Pyrantel……..(as embonate)

(equivalent to 360 mg of oxantel embonate) 124.85 mg

Praziquantel …….. 125.00 mg

Excipient QS for one pre-scored 2375-mg tablet

For the full list of excipients, see 'List of excipients' section.

3. Pharmaceutical form

Tablet.
Pale yellow to yellow oblong tablet with breaking line.

4. Clinical particulars

4.1. Target species

Dogs.

4.2. Indications for use, specifying the target species

For curative treatment of dogs harbouring mixed parasitic infestations with the following adult stages of nematodes and cestode species :
Nemtodes :
toxocara canis, toxocaris leonine, ancylostoma caninum, uncinaria stenocephala, trichuris vulpis.
Cestodes :
Dipylidum caninum taenia spp.

4.3. Contraindications

See 'Interaction with other medicinal products and other forms of interactions' section.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings for each target species

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

As fleas serve as intermediate hosts for one of the common tapeworms (*Dipylidium caninum*) tapeworm infestation may reoccur if the intermediate hosts are not controlled.

4.5. Special precautions for use

i) Special precautions for use in animals

Roundworm and Hookworm infestation:
In some animals, *Ancylostoma caninum* and *Toxocara canis* may not be totally eradicated by the treatment, resulting in a continued risk of shedding eggs into the environment.
After treatment, an examination of the faeces is advisable and according to the results of these examinations, treatment with a nematodicidal product may be started, if necessary.

Treating pups younger than two months old or weighing less than 1 kg is not recommended.

In heavily infested or weakened animals, the product should be used only after a veterinarian has carried out a benefit/risk assessment.

Do not use in animals with known hypersensitivity to one of the ingredients of the product.

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

Some components of this product may cause allergic reactions or skin irritation.
Avoid contact with the skin.
People with known hypersensitivity to one of the ingredients should avoid all contact with this product.
Wash hands after use.
In case of accidental ingestion, consult a doctor and show them the patient information leaflet.

iii) Other precautions

None.

4.6. Side effects (frequency and seriousness)

Vomiting and diarrhoea may occur following the treatment.
Anorexia is a known adverse effect of products containing praziquantel. As a result, although not described in studies conducted on the product, anorexia may be observed.

Reporting of suspected adverse reactions

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

4.7. Use during pregnancy, lactation, or lay

The safety of this veterinary medicinal product for pregnant or lactating animals has not been established. Use of this product is not recommended during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with levamisole, piperazine or cholinesterase inhibitors.

4.9. Amounts to be administered and administration route

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.

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

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

4.11. Withdrawal period(s)

Not applicable.

5. Pharmacological properties

Pharmacotherapeutic group: Praziquantel, combinations.
ATCvet code: QP52AA51.

5.1. Pharmacodynamic properties

This medicinal product contains three active ingredients: pyrantel and oxantel as embonate, and praziquantel. The spectrum of activity of the product is wide and it targets gastrointestinal nematodes (ascarids, whipworm and hookworms) and cestodes.

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

Oxantel is an m-oxyphenolic derivative of pyrantel, developed for its activity against whipworms.

Praziquantel triggers muscle contractions, paralysis and alters the integrity of the tegument in parasites. It is active against adults and larval stages of dog cestodes, *Echinococcus, Taenia* and *Dipylidium.*

5.2. Pharmacokinetic particulars

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

6. Pharmaceutical particulars

6.1. List of excipients

Dextrates
Povidone K30
Sodium lauryl sulphate
Crospovidone
Sodium stearyl fumarate

Bacon flavour

6.2. Major incompatibilities

None known.

6.3. Shelf life

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

6.4. Special precautions for storage

Store below 25◦C

6.5. Nature and composition of immediate packaging

Polychlorotrifluoroethylene-PVC/aluminium blister

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

The empty packaging and any remaining product should be disposed of in accordance with current practices governed by the regulations on waste materials.

7.

Manufacturer:

VETOQUINOL
MAGNY VERNOIS
70200 LURE, FRANCE

Registration license holder:

ELIEZER LINEVITZ LTD., KANOT INDESTRIAL AERA, ADOM 6 ST., P.O.B 7006, ISRAEL

Registration numbers:

DOLPAC 10 VETERINARY: 142-76-92430

DOLPAC 25 VETERINARY: 142-77-92433

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