SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Austria Belgium Cyprus Malta Czech Republic Netherlands Greece Portugal Slovakia Hungary Slovenia Germany Finland	Dolpac large dogs tablets
France Luxembourg	Dolpac 25 comprimé
UK-Ireland-Italy	Dolpac Tablets for Large Dogs
Poland Spain	Dolpac large dogs tablets for 20-75 kg
Denmark Sweden	Dolpac vet large dogs tablets

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

Excipient to one 2375 mg divisible tablet

Excipients
For a full list of excipients, see section 6.1

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 nematode and cestode species:

Nematodes:

Toxocara canis
Toxascaris leonina
Ancylostoma caninum
Uncinaria stenocephala
Trichuris vulpis

Cestodes:

Dipylidium caninum
Taenia spp
Echinococcus multilocularis
Echinococcus granulosus

4.3 Contraindications

See section 4.8

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

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 product may be carried out if necessary.

The 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, the product should be used only according to a benefit/risk assessment by the responsible veterinarian.

Do not use in animals with known hypersensitivity to any of the components of the product.

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

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

Avoid contact with the skin.

People with known hypersensitivity to any of the ingredients should avoid contact with this product.
Wash hands after use.
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea may be observed following the treatment.
Despite not being observed in studies performed with the product, anorexia can occur as it is a common adverse effect of products containing praziquantel.

4.7 Use during pregnancy, lactation or lay

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

4.9 Amounts to be administered and administration route

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, by oral route.

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.

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

Administration of the product to healthy dogs at 5 times the recommended dosage 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

The product contains three active ingredients, pyrantel embonate, oxantel embonate and praziquantel. The spectrum of activity of the 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*.

5.2 Pharmacokinetic particulars

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrates
Povidone K30
Sodium lauryl sulphate
Bacon flavour
Crospovidone
Sodium stearyl fumarate

6.2 Incompatibilities

None applicable

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: three years
Discard any unused half tablet

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4121

9. DATE OF FIRST AUTHORISATION

14 January 2008

10. DATE OF REVISION OF THE TEXT

October 2011