OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Austria Belgium Cyprus Malta Czech Republic Netherlands Greece Portugal Slovakia Hungary Slovenia Germany Finland	Dolpac medium dogs tablets
France Luxembourg	Dolpac 10 comprimé
UK-Ireland-Italy	Dolpac Tablets for Medium Dogs
Spain Poland	Dolpac medium dogs tablets for 5-20 kg
Denmark Sweden	Dolpac vet medium dogs tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances

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

Excipient to one 950 mg divisible tablet

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

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
Cardboard box with 1 strip of 6 tablets
Cardboard box with 3 strips of 6 tablets
Cardboard box with 5 strips of 6 tablets
Cardboard box with 10 strips of 6 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

Not included.

7. METHOD AND ROUTE OF ADMINISTRATION

Oral route.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:
Discard any unused half tablet

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder

Manufacturer for the batch release:
VETOQUINOL
MAGNY VERNOIS
F-70200 LURE

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3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains
Active substances

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Pyrantel	49.94 mg (equivalent to 144 mg of pyrantel embonate)
Praziquantel	50.00 mg

Excipient to one 950 mg divisible tablet

4. INDICATIONS

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

See paragraph “Special warnings”.

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dose rate is 20 mg oxantel / 5 mg pyrantel / 5 mg praziquantel per kg bodyweight, ie one tablet per 10 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 3.1 to 5 kg	½
From 5.1 to 10 kg	1
From 10.1 to 20 kg	2
From 20.1 to 30 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

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date which is stated on the carton after EXP
Discard any unused half tablet

12. SPECIAL WARNINGS

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.

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.

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.

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

Interaction with other medicinal products and other forms of interaction
Do not use simultaneously with levamisole, piperazine or choline esterase inhibitors

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box with 1 strip of 3 tablets
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Cardboard box with 20 strips of 3 tablets
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Cardboard box with 3 strips of 6 tablets
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Cardboard box with 10 strips of 6 tablets
Not all pack sizes may be marketed.

BLISTER

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2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.