Consumer Leaflet for a Veterinary Product
This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. Name of the veterinary medicine, form and strength

Drontal Plus Flavoured, Veterinary

Tablets

2. **Active ingredients** and quantity in a single dose:

Each tablet contains:

Active ingredients:

Febantel 150 mg

Pyrantel Embonate 144 mg

Praziquantel 50 mg

Inactive ingredients:
Artificial beef flavour irradiated 116.5 mg
For a full list of excipients, see section 13: "additional information".

3. What is the medicine intended for

Flavoured tablets for the treatment of tapeworms and roundworms in dogs, including the worms types:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms)

Hookworms: *Uncinaria stenocephala, Ancylostoma caninum* (adults)

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Echinococcus* species, *Taenia species, Dipylidium* species (adult and immature forms).

Therapeutic group: Anthelmintic.

Febantel - for the control of roundworms
Pyrantel Embonate- for the control of roundworms

Praziquantel- for the control of tapeworms

4. Contra-indications

Do not use simultaneously with piperazine compounds.

5. Side effects

In very rare cases slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

Reporting of suspected adverse reactions

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Repot" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link:

https://sideeffects.health.gov.il/

Side effects can also be reported to Lidorr Elements, by email to: lidorvet@lidorr.com

6. Target animals

Dogs.

7. Dosage and administration

According to the veterinarian's instructions.

One tablet per 10 kg bodyweight.

The tablet can be given directly, or disguised in food. Fasting is not required before or after treatment.

Puppies and small dogs:

3-5 kg bodyweight = ½ tablet

Over 5 kg – 10 kg bodyweight = 1 tablet

Medium dogs:

Over 10 kg – 15 kg bodyweight = 1 ½ tablets

Over 15 kg – 20 kg bodyweight = 2 tablets

Over 20 kg – 25 kg bodyweight = 2 ½ tablets

Over 25 kg – 30 kg bodyweight = 3 tablets

Large dogs:

Over 30 kg – 35 kg bodyweight = 3 ½ tablets

Over 35 kg – 40 kg bodyweight = 4 tablets

For the treatment of *Toxocara*, nursing bitches should be dosed two weeks after giving birth, and then every two weeks until the puppies are weaned. Treatment of puppies should be started at age of 2 weeks, and then every two weeks until 12 weeks of age. Thereafter, treatment should be given every three months. It is recommended to treat the puppies and their mother at the same time. Adult dogs should be treated every three months. In cases of severe roundworm infection, a repeat dose should be given after two weeks.

8. How to use the product

See section 7: " Dosage and administration"

9. Withdrawal period

Not applicable.

10. Warnings

- Special warnings for use of the medicine in target **animals**

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum.* Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice etc is undertaken.

- **Special precautions for safety use in animals**

Not for use in dogs weighing less than 3 kg.
Any part used tablet should be discarded.

- **Special precautions to be taken by the person administering the medicinal product to animals**

In the interests of good hygiene, persons administering the tablet directly to the dog or by adding it to the dog's food, should wash their hands afterwards.

- **Pregnancy and lactation in target animals**

Do not exceed the stated dose when treating pregnant bitches.
Consult a veterinary surgeon before treating pregnant animals for roundworms.
The product may be used during lactation**.**

- **Interaction with other medicinal products and other forms of interaction**

Do not use simultaneously with piperazine compounds.

- **Overdose**

The product is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

- **Incompatibilities**

Not applicable.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children

and/or infants to prevent accidental poisoning.

- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store at room temperature, below 25°C.

12. Instructions for disposing of the product / remaining product at the end of its use

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- in addition to the active ingredient, this medicine also contains:

Maize starch, Artificial beef flavor irraditated, Lactose monohydrate, Microcristalline cellulose, Povidone, Magnesium stearate, Sodium lauryl sulphate, Colloidal anhydrous silica.

- How does the medicine look like and what is the content of the package:

Carton boxes containing 24 or 104 tablets, packed in blisters.
Not all pack sizes may be marketed.
The tablets are light brown to brown, round, flat, cross scored on one side.

- **Registration holder name and address:**

Lidorr Elements Ltd.
63 HaNevi'im st., Ind.Area Morasha, Ramat HaSharon.

- **Manufacturer name and address:**

Bayer Animal Health GmbH
D-51368 LEVERKUSEN, GERMANY

- **Registration number of this medicine in the Ministry of Health State Medicine Registry:**

081 95 92122

Revised in February 2022 according to MoH guidelines.