Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Plerion chewable tablets for dogs from 2.5 kg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:
Pyrantel (as embonate) 25 mg
Oxantel (as embonate) 100 mg
Praziquantel 25 mg

Excipients:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets
Brown, slightly speckled and oblong in shape.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of dogs harbouring mixed parasitic infestations with the following adult stages of nematode and cestode species:

Ascarids: *Toxocara canis, Toxascaris leonina*
Hookworms: *Uncinaria stenocephala, Ancylostoma caninum*
Whipworms: *Trichuris vulpis*
Tapeworms: *Dipylidium caninum, Mesocestoides* spp., *Taenia ovis, Taenia pisiformis, Taenia hydatigena, Taenia multiceps, Echinococcus* spp.

4.3 Contraindications

Do not use in dogs younger than 2 months of age.
Do not use in dogs weighing less than 2.5 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients .
For use during pregnancy or lactation, see section 4.7.

4.4 Special warnings for each target species

Roundworm and Hookworm infections:
In some animals, *Ancylostoma caninum* and *Toxocara canis* may not be totally eradicated by the treatment, resulting in a continued risk of shedding of eggs into the environment. Follow-up examinations of the faeces are advisable and, based on the results of these examinations, treatment with a nematodicidal product should be carried out, if necessary.

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

When *D. caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection.

Dogs kept together or in kennels should be treated at the same time.

4.5 Special precautions for use

Special precautions for use in animals

In debilitated or heavily infested animals, the product should be used only according to a benefit-risk assessment by the responsible veterinarian.

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

Do not eat or drink while handling the veterinary medicinal product.
Wash your hands thoroughly with water and soap immediately after use of the veterinary medicinal product.
This veterinary medicinal product may cause irratation to eyes, any contact with the eyes should be avoided while usint the veterinary medicinal product. If eye contact occurs, flush eyes immediately with plenty of water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In rare occasions vomiting and diarrhoea may be observed following the treatment.
Although not observed in studies performed with this product, anorexia may occur as it is a common adverse effect of products containing praziquantel.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in bitches during pregnancy and lactation.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian .

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

Single oral administration.

The recommended dose rate is 5 mg pyrantel + 20 mg oxantel + 5 mg praziquantel per kg bodyweight, i.e. 1 tablet per 5 kg b.w. according to the dosage scheme proposed in the table below:

Body weight of dogs	Quantity of tablets
2.5 – 5 kg	1
6 – 10 kg	2
11 – 15 kg	3

The chewable tablets contain a flavour and are taken voluntarily by most dogs. The tablets can be given directly to the dog or with food.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

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

In safety studies overdoses of three times the highest recommended dose of 10 mg pyrantel, 40 mg oxantel and 10 mg praziquantel per kg bodyweight or overdoses of the highest recommended dose given for 3 consecutive days led to sporadic vomiting or soft faeces. These clinical signs resolved without further treatment.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: anthelmintics, Quinoline derivatives and related substances, Praziquantel, combinations.
ATCvet code: QP52AA51

5.1 Pharmacodynamic properties

Pyrantel is a member of the tetrahydropyrimidine class. While this compound is effective against common ascarids and hookworms of dogs, it has very limited efficacy against whipworms and no efficacy against tapeworms. Pyrantel affects the neuromuscular system of susceptible parasites by exerting an irreversible, nicotinic effect on the neuromuscular junction leading to spastic paralysis of the worm.

Oxantel also belongs to the tetrahydropyrimidine group. It exerts anthelmintic activity in nematodes belonging to the family Trichuridae, such as *Trichuris vulpis*. The mode of action is, like that of pyrantel, related to its ability to induce depolarisation of the neuromuscular junction and progressive contraction of parasite muscle leading to spastic paralysis.

Praziquantel, a quinoline derivative, is effective against adult and larval stages of a number of cestodes. After being rapidly absorbed by the parasite, praziquantel leads to spastic contraction of the parasite musculature and vacuolisation of the syncytial tegument.

5.2 Pharmacokinetic properties

The data available indicate poor absorption of oxantel embonate and pyrantel embonate from the gastrointestinal tract, with high concentrations reached in the gastro-intestinal tract including colon and caecum, the location of the parasites. Following oral administration of Plerion, praziquantel given at 5 mg/kg is quickly absorbed reaching average peak plasma concentrations of 0.14 µg/ml after 3 hours, is metabolized and is rapidly eliminated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pig liver flavour
Macrogol 3350
Sucrose
Sodium laurilsulfate
Magnesium stearate
Aspartame
Soya-bean oil (stabilised with butylhydroxytoluene)
Glycerol
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original container in order to protect from light.

6.5 Nature and composition of immediate packaging

PVC/PVDC/aluminium heat sealed peelable blisters.
Carton boxes containing:
2 tablets (1 blister with 2 tablets),
20 tablets (10 blisters with 2 tablets),
160 tablets (20 blisters with 8 tablets) and
200 tablets (25 blisters with 8 tablets)

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/211/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th February 2009
Renewal of the last authorisation: 17th January 2014

10 DATE OF REVISION OF THE TEXT