

Plerion 5

chewable tablets for dogs

Plerion 10

chewable tablets for dogs

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

Marketing authorisation holder:

Marketing Authorisation Holder in the UK:

Intervet UK Ltd
Walton Manor, Walton, Milton Keynes, MK7 7AJ

Marketing Authorisation Holder in Ireland and Licensed distributor in Northern Ireland:

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

Manufacturer for the batch release:

Intervet GesmbH
Siemensstraße 107, 1210 Vienna, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Plerion 5 chewable tablets for dogs
Plerion 10 chewable tablets for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each brown, slightly speckled and oblong in shape chewable tablet (Plerion 5) contains:
25 mg pyrantel (as embonate)
100 mg oxantel (as embonate)
25 mg praziquantel

Each brown, slightly speckled and round in shape chewable tablet (Plerion 10) contains:
50 mg pyrantel (as embonate)
200 mg oxantel (as embonate)
50 mg praziquantel

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in dogs younger than 2 months of age.

Plerion 5: Do not use in dogs weighing less than 2.5 kg.

Plerion 10: Do not use in dogs weighing less than 5 kg.

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

For use during pregnancy or lactation, see section 12.

6. ADVERSE REACTIONS

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.

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

Single oral administration.

The recommended dose rate is 5 mg pyrantel + 20 mg oxantel + 5 mg praziquantel per kg bodyweight, i.e. 1 Plerion 5 tablet per 5 kg b.w., or 1 Plerion 10 tablet per 10 kg b.w. according to the dosage scheme proposed in the table below.

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

9. ADVICE ON CORRECT ADMINISTRATION

The administration should follow the dosage scheme proposed in the table below:

Body weight of dogs	Quantity of Plerion 5 tablets	Quantity of Plerion 10 tablets
2.5 – 5 kg	1	
5 – 10 kg	2	1
11 – 15 kg	3	
11 – 20 kg		2
21 – 30 kg		3
31 – 40 kg		4
41 – 50 kg		5
51 – 60 kg		6
61 – 70 kg		7

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.

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 temperature storage conditions.

Store in the original container in order to protect from light.

Do not use after the expiry date stated on the carton.

12. SPECIAL WARNING(S)

Target species warnings:

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.

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 nematocidal product should be carried out, if necessary. In debilitated or heavily infested animals, the product should be used only according to a benefit/risk assessment by the responsible veterinarian.

The safety of the 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 veterinary surgeon.

Do not use simultaneously with levamisole, piperazine or choline esterase inhibitors. In safety studies overdoses of 3 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.

User warnings:

Do not eat or drink while handling the product.

Wash your hands thoroughly with water and soap immediately after use of the product.

This veterinary medicinal product may cause irritation to eyes, any contact with the eyes should be avoided while using the product. If accidental eye contact, 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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2008

15. OTHER INFORMATION

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.

In the UK:

Plerion 5: Vm 01708/4543
Plerion 10: Vm 01708/4544

NFA-VPS

In Ireland:

Plerion 5: VPA 10996/211/001
Plerion 10: VPA 10996/211/002

CAM

Companion Animal Medicine