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Anthelmin Plus Flavour & Anthelmin Plus XL Tablets

Species:Dogs

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Anthelmintics for dogs

Active ingredient:Febantel, Praziquantel, Pyrantel Embonate

Product:Anthelmin Plus Flavour & Anthelmin Plus XL Tablets

Product index:Anthelmin Plus Flavour Tablets for Dogs

Incorporating:

Presentation

Anthelmin Plus Flavour Tablets for Dogs - yellow, round, biconvex tablets with visible darker spots, cross-scored line on one side and plain on other side. The tablets can be divided into equal halves or equal quarters. The tablets contain Praziquantel 50mg, Pyrantel embonate 144mg and Febantel 150mg with excipients.

Anthelmin Plus XL Tablets for Dogs - slightly greenish yellow, oval, biconvex tablets with bevelled edges and scored on both sides. The tablets can be divided into equal halves. The tablets contain Praziquantel 175mg, Pyrantel embonate 504mg and Febantel 525mg with excipients.

Uses

Anthelmin Plus Flavour & Anthelmin Plus XL - For the treatment of mixed infestations with the following roundworms and tapeworms in adult dogs and puppies:

Nematodes - Ascarids: *Toxocara canis*, *Toxascaris leonina* (late immature forms and mature forms).

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

Cestodes - Tapeworms: *Taenia* spp., *Dipylidium caninum*

Dosage and administration

Dosage:

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For oral use.

Anthelmin Plus Flavour – Puppies may be wormed with this veterinary medicinal product from 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 monthly intervals until 6 months of age.

For treatment of dogs administer 1 tablet per 10kg bodyweight (15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel). This is equivalent to 1 tablet per 10 kg bodyweight. Tablets may be halved/quartered to allow accuracy of dosing.

Anthelmin Plus XL - Minimum dog weight 17.5Kg. 1 tablet per 35 kg bodyweight. Tablets may be halved to allow accuracy of dosing.

Bodyweight (kg)	Anthelmin Plus (1 tablet=10kg)	Anthelmin Plus XL (1 tablet=35kg)
	Tablet Quantity	
2.5	0.5	-
>5-10	1	-
>10-15	1.5	-
>15-20	2	-
>20-25	2.5	1
>25-30	3	1
>30-35	3.5	1
>35-40	4	1.5
>40-45	4.5	1.5
>45-50	5	1.5
>50	5.5	2

Administration:

The tablet(s) can be given directly to the dog or disguised in food. No restriction of access to food is required either before or after administration of the veterinary medicinal product. To ensure a correct dosage, body weight should be determined as accurately as possible. Puppies may be wormed with this veterinary medicinal product from 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 monthly intervals until 6 months of age.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning. For adult dogs, a single dose should be used. The advice of a veterinarian should be sought regarding the need for and frequency of repeat treatment. In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

Use during pregnancy and lactation

Anthelmin Plus Flavour and Anthelmin Plus XL - Consult a veterinary surgeon before treating pregnant animals for roundworms.

Do not use the product in the first two thirds of pregnancy. The product may be used during lactation.

Contra-indications, warnings, etc

Do not use simultaneously with piperazine compounds.

Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

Do not exceed the stated dosage when treating pregnant bitches.

Do not use in dogs younger than 2 weeks of age and/or weighing less than 2 kg.

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Anthelmin Plus XL is not recommended for use in dogs under 17.5 kg bodyweight.

Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken. Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions for safe use in the target species:

Any part-used tablets should be discarded.

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

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse events Dogs: In very rare cases, transient loose faeces, diarrhoea and/or vomiting may occur

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details

Symptoms of overdose

Benzimidazoles possess wide safety margin. Pyrantel is not absorbed systematically to any extent. Praziquantel also has a wide safety margin, of up to five times the recommended dose.

Veterinary medicinal product is well tolerated in dogs. In safety studies of up to five times the recommended dose gave rise to occasional vomiting.

Interactions with other medicinal products and other forms of interaction

Do not combine with piperazine as the anthelmintic effects of pyrantel and piperazine (used in many worming products for dogs) may be antagonized. Concurrent use with other cholinergic compounds can lead to toxicity.

Pharmaceutical precautions

Store in the original packaging in order to protect from light and moisture.

Shelf-life of unopened package: 3 years.

Legal category

Legal category: NFA-VPS

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Packaging quantities

Anthelmin Plus Flavour - 4 and 100 tablet packs

Anthelmin Plus XL - 12 tablet pack

Marketing Authorisation Holder (if different from distributor)

KRKA, d.d., Novo mesto

Šmarješka cesta 6

8501 Novo mesto

Slovenia

Further information

Pharmacotherapeutic group: Anthelmintics, Benzimidazoles and related substances

ATCvet code: QP52AC55

The veterinary medicinal product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances: febantel, pyrantel embonate (pamoate) and praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use. Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow removal from the gastro-intestinal (GI) system by peristalsis.

With the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerization. Formation of microtubules is thereby prevented, resulting in disruption to structures vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later.

Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both *in vitro* and *in vivo* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination product pyrantel and febantel act synergistically against all relevant nematodes (ascarids and hookworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala* and *Ancylostoma caninum*. The spectrum of activity of praziquantel covers also cestode species in dogs, in particular all *Taenia* spp. and *Dipylidium caninum*. Praziquantel acts against adult and immature forms of these parasites.

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized into inactive forms in the

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liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.

The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Because of the low systemic absorption of pyrantel pamoate, there is very little danger of adverse reactions/toxicity in the host. Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.

Febantel is absorbed relatively rapidly and metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.

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

Medicines should not be disposed of via wastewater. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

List of Excipients:

Lactose monohydrate, Maize starch, Povidone K-30, Sodium laurilsulfate, Microcrystalline cellulose (E460), Colloidal anhydrous silica, Magnesium stearate (E572), Meat flavour.

Marketing Authorisation Number

Anthelmin Plus Flavour Vm 01656/4015

Anthelmin Plus XL Vm 01656/4016

Significant changes

GTIN

GTIN description:Anthelmin Plus Flavour Tablets for Dogs 4 tablet pack

GTIN:03838989651817

GTIN description:Anthelmin Plus Flavour Tablets for Dogs 100 tablet pack

GTIN:03838989651824

GTIN description:Anthelmin Plus XL Tablets for Dogs 12 pack

GTIN:03838989651831