1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Dog Tasty Bone XL 525/504/175 mg tablets [IE]
Mansonil All Worm Large Dog Tasty525/504/175 mg tablets [NL]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances
525 mg febantel
175 mg pyrantel equivalent to 504 mg pyrantel embonate
175 mg praziquantel

Excipients
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A light-brown to brown, meat flavoured, bone shaped tablet scored on both sides that can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of mixed infections by nematodes and cestodes of the following species:

Roundworms:	
Ascarids (adult and late immature forms) :	*Toxocara canis, Toxascaris leonina*
Hookworms (adults):	*Uncinaria stenocephala, Ancylostoma caninum*
Whipworms (adults):	*Trichuris vulpis*
Tapeworms (adult and immature forms):	*Echinococcus granulosus* *Echinococcus multilocularis* *Dipylidium caninum* *Taenia* spp.

4.3 Contraindications

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

Do not use during the 1st and 2nd third of pregnancy (see section 4.7).

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

To minimise the risk of reinfestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Other precautions

Since it contains praziquantel, the product is effective against *Echinococcus* spp. which do not occur in all EU member states but are becoming more common in some. 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases mild 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.

The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.

The safety of the product has not been investigated during the 1st and 2nd third of pregnancy. Do not use in pregnant dogs during the 1st and 2nd third of pregnancy (see section 4.3).

A single treatment during the last third of pregnancy or during lactation has been demonstrated safe.

4.8 Interaction with other medicinal products and other forms of interaction

The anthelmintic effects of this product and piperazine containing products may be antagonised when the two drugs are used together.
Concurrent use with other cholinergic compounds can lead to toxicity

4.9 Amounts to be administered and administration route

For oral administration only.

Dosage

For treatment of dogs, 1 tablet per 35 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight).

Dosages are as follows:

Body weight (kg)	Tablet quantity
7-17.5	½
>17.5-35	1
>35-52.5	1 ½
>52.5-70	2

For each additional 17.5 kg bodyweight, administer an additional half tablet.

Administration and Duration of Treatment

The tablets are flavoured and studies have shown that they are highly palatable and are taken voluntarily by the majority (88%) of dogs tested.
The tablets can be administered with or without food. Access to normal diet does not need to be limited before or after treatment.

Tablets should be given as a single administration.

Any unused half-tablets should be discarded immediately or returned to the open blisters for use within 7 days.

The advice of a veterinarian should be sought regarding the need for and frequency of repeat treatment.

Not for use in dogs weighing less than 7 kg.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

No signs of adverse reactions were observed in safety studies in dogs and pups following administration of 10 times the recommended dose of the product.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, praziquantel combinations.
ATCvet code: QP52AA51.

5.1 Pharmacodynamic properties

The product is an anthelmintic containing as active substances the tetrahydropyrimidine derivative pyrantel (as the embonate salt), the pro-benzimidazole febantel and praziquantel, a partly hydrogenated pyrazinoisoquinoline derivative. It is effective against certain roundworms and tapeworms.

In this fixed combination pyrantel and febantel act synergistically against roundworms (ascarides, hookworms and whipworms) in dogs. In particular, the action spectrum covers *Toxocara canis, Toxascaris leonina, Uncinaria stenocephala, Ancylostoma caninum,* and *Trichuris vulpis*.

The spectrum of activity of praziquantel covers tapeworm species in dogs. In particular, it includes all *Taenia* species, as well as *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis.* Praziquantel acts against all intestinal stage of these parasites.

Pyrantel acts as a nicotinic agonist at acetylcholine receptors, causing spastic paralysis of roundworms via a depolarising neuromuscular block.

The anthelmintic efficacy of febantel is due to its ability to inhibit the polymerisation of tubulin to microtubuli. The resulting structural and functional metabolic disturbances exhaust the parasite's energy reserves and kill it in 2-3 days.

Praziquantel is absorbed very rapidly through the parasite's surfaces and is evenly distributed throughout their bodies. It causes severe damage of their integument, leading to disruption of metabolism and subsequently to death.

5.2 Pharmacokinetic particulars

Praziquantel is absorbed almost completely in the small intestine following oral administration to dogs. Absorption is very rapid reaching maximum serum levels within 0.5 to 2 hours. After absorption, the drug is widely distributed through the body. Plasma protein binding is high. Praziquantel is rapidly metabolised in the liver leading to inactive metabolites. In dogs, metabolites are eliminated by urine (66 % of an oral dose) and via the bile (15%) in the faeces. Elimination half-life in dogs is about 3 hours.

Pyrantel (as embonate), being a low water-soluble compound, is poorly absorbed in the gastrointestinal tract, reaching the final parts of the intestine. The absorbed drug is extensively metabolised and the parent compound/metabolites are excreted by urine.

Febantel is a pro-drug that after oral administration and oral absorption is metabolised to fenbendazole and oxfendazole, the chemical entities exerting the anthelmintic effect. The active metabolites are excreted via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Sodium laurilsulfate
Colloidal anhydrous silica
Croscarmellose sodium
Meat flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life of half-tablets after first opening the immediate packaging: 7 days

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Container material: Blisters formed from PA/Alu/PE foil and sealed with Alu/PE foil.

Container sizes : Cartons containing 2 tablets.

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

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

[Completed Nationally]

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE