SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parazole Dog/Cat 100 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Fenbendazole 100 mg

Excipients
Methyl Parahydroxybenzoate (E218) 2.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
A white to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of domestic dogs and cats infected with immature and mature stages of nematodes of the gastrointestinal and respiratory tracts. Effective against immature and mature ascarids, hookworms and tapeworms. Also kills roundworm eggs.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight or misadministration of the product.

4.5 Special precautions for use

Special precautions for use in animals:
Ensure correct weight estimation and dose calculation.

Special precautions to be taken by the person administering the product to animals:
People with known hypersensitivity to fenbendazole or any of the excipients should avoid contact with the veterinary medicinal product.
Impermeable gloves should be worn to avoid skin contact with the product. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.
It is advisable that the product is not mixed with other medicinal products.

4.9 Amounts to be administered and administration route

Dose for routine worming of adult dogs and cats:

Shake well before use and administer a single dose at a dose rate of 100 mg/kg body weight which is equivalent to 1 ml per 1 kg body weight.

Dosage chart examples:

	Bodyweight	**Volume of Parazole**
Adult Cat	2kg	2ml
	4kg	4ml
	6kg	6ml
Small Dog	3kg	3ml
	5kg	5ml
Medium Dog	15kg	15ml
	25kg	25ml
Large Dog	35kg	35ml
	40kg	40ml

Dose rate for weaned puppies and kittens under six months of age and lungworms in cats:

Shake well before use and administer a single dose for 3 consecutive days at a rate of 50 mg/kg body weight which is equivalent to 1 ml per 2kg body weight.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises. Treatment may also be required at 8 weeks and 12 weeks of age.

Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where reinfestation occurs more readily.

Dose rate for pregnant bitches:

Shake well before use and administer 1ml per 4 kg body weight daily from day 40 of pregnancy continuously for approximately 25 days. This is equivalent to 25 mg fenbendazole /kg body weight daily.

For oral administration only.

Fenbendazole can be administered orally either directly into the mouth or alternatively it can be mixed in feed. Good mixing of the product in feed is advisable.

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

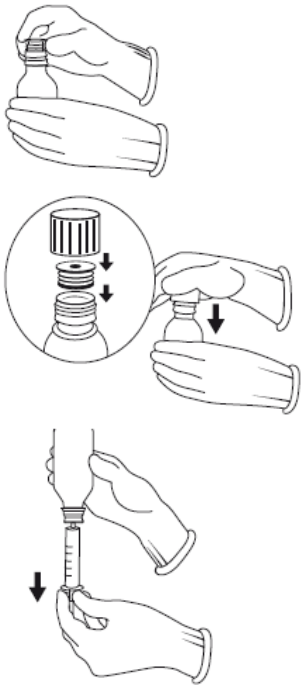
The suspension can be given using the 12 ml measuring syringe provided in the package. A syringe adaptor luer is also provided in the package.

Dosing procedure using the measuring syringe:

1. Estimate the body weight of the dog or cat accurately to ensure correct dosage.

2. To insert the syringe adapter (bung): Push down and unscrew bottle top. Position the syringe adapter (bung) and cap over the bottle opening. Push down firmly and screw cap into position. Syringe adapter (bung) should now be flush with the top of the bottle neck.

3. Shake bottle well before use. Push down and unscrew the bottle top. Insert the nozzle of the measuring syringe into the hole in the bung by gently pushing.



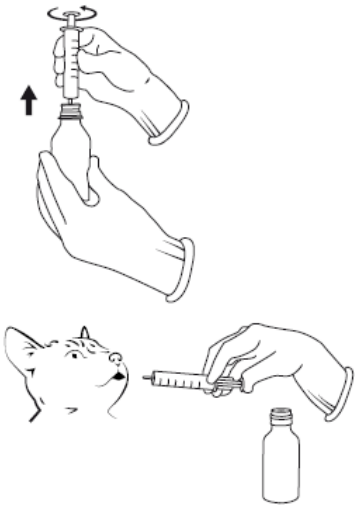
4. Turn the bottle/syringe upside down. Pull the syringe plunger out until the plunger corresponds to the required dose.

5. Turn the bottle right way up and with a twisting movement separate the measuring syringe from the bottle.

6. Push the plunger to empty the contents of the syringe directly into the mouth of the animal or onto the food. Good mixing of the product in food is advisable if it is to be given this way.

7. Depending on the dose required, repeat steps 3-6.

8. Replace bottle top after use.



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

Benzimidazoles have a wide safety margin. It has been shown that at dosages up to 125 mg per kg, no toxic effect was observed. Little information is available for the cat – however fenbendazole is well tolerated at 150 mg/kg daily for 3 days.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC vet code: QP52AC13

5.1 Pharmacodynamic properties

Fenbendazole is an established anthelmintic which belongs to the benzimidazole group and is used primarily for its activity against nematodes.

Fenbendazole is an anthelmintic of the benzimidazole carbamate group which disrupts the energy metabolism of nematodes. The underlying mechanism of the anthelmintic action of fenbendazole is inhibition of the polymerisation of tubulin to microtubules. Fenbendazole is effective against adult and immature gastrointestinal nematodes.

Fenbendazole displays preference for parasitic as opposed to mammalian tubulin; this appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

5.2 Pharmacokinetic properties

After oral administration fenbendazole is absorbed slowly and only partially. Following absorption from the digestive tract fenbendazole is metabolised in the liver to sulphoxide (oxfendazole) and further to sulphone and amine derivatives. Fenbendazole and its metabolites disperse slowly throughout the body, reaching high concentrations in the liver. Unchanged and metabolised fenbendazole is excreted primarily (>90%) with the faeces, and to a small extent also via the urine and milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Methyl Parahydroxybenzoate (E218)
Polysorbate 80
Xanthan Gum
Simethicone Emulsion
Purified Water

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

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

Shelf- life after first opening the container: 6 months

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

White, high density polyethylene bottle of 100 ml size with tamper evident child resistant closure.
Each 100 ml bottle is packed in a cardboard box and is supplied with a 12 ml polyethylene measuring syringe and a low density polyethylene syringe adaptor luer.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Foran Healthcare
Red Mills
Goresbridge
Kilkenny
R95 EKH4
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 18576/4000

9. DATE OF THE FIRST AUTHORISATION

22 August 2018

10. DATE OF REVISION OF THE TEXT

February 2024