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: 100 mg fenbendazole

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	2.5 mg
Propylene glycol	
Polysorbate 80	
Xanthan gum	
Simethicone emulsion	
Purified water	

A white to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each 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.

3.3 Contraindications

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

3.4 Special warnings

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 veterinary medicinal product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Ensure correct weight estimation and dose calculation.

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

People with known hypersensitivity to fenbendazole or any of the excipients should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:
None known.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

Lactation:

Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

It is advisable that the veterinary medicinal product is not mixed with other veterinary medicinal products.

3.9 Administration routes and dosage

Oral use.

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

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	2 kg	2 ml
	4 kg	4 ml
	6 kg	6 ml
Small Dog	3 kg	3 ml
	5 kg	5 ml
Medium Dog	15 kg	15 ml
	25 kg	25 ml
Large Dog	35 kg	35 ml
	40 kg	40 ml

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 2 kg 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 1 ml 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.

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

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.

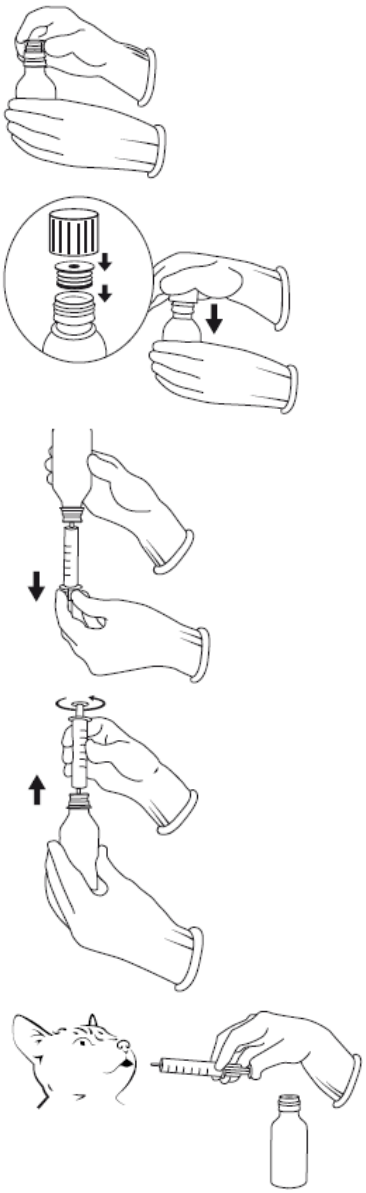
4. Turn the bottle/syringe upside down. Pull the syringe plunger out until the plunger corresponds to the required dose.

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 veterinary medicinal 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.



3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Benzimidazoles have a wide safety margin. It has been shown that at dosages up to 125 mg/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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not freeze.

5.4 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.

5.5 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 or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Foran Healthcare

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).