

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parazole Dog/Cat 100 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of fenbendazole.

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

Wormer for dogs & cats.

Effective Against:

Roundworms

Tapeworms

Hookworms

Lungworms

Roundworm eggs

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

Once opened use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Foran Healthcare
or



14. MARKETING AUTHORISATION NUMBER

Vm 18576/4000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parazole Dog/Cat 100 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of fenbendazole.

3. TARGET SPECIES

Dogs and cats

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Foran Healthcare

Or



9. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Parazole Dog/Cat 100 mg/ml Oral Suspension

2. Composition

Each ml contains:

Active substance:
100 mg of fenbendazole

Excipient:
2.5 mg of methyl parahydroxybenzoate

A white to off-white suspension.

3. Target species

Dogs and cats.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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.

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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 medicinal products.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Dogs and cats:

None known.

Reporting adverse events is important. It allows for continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via the national reporting system:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

UK

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

Dosage

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

Routine treatment of adult dogs and cats:

A single dose at a dose rate of 100 mg/kg which is equivalent to 1 ml per 1 kg body weight.

See dosage chart below for examples:

	Body weight	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

Weaned puppies and kittens under six months of age and lungworm in cats:

A single dose for three consecutive days at a dose rate of 50 mg/kg 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.

Pregnant bitches:

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.

Regular treatment is advisable to prevent infection of children by the larvae of ascarids of dogs and cats.

Method and route of administration:

Administer orally or mix in feed.

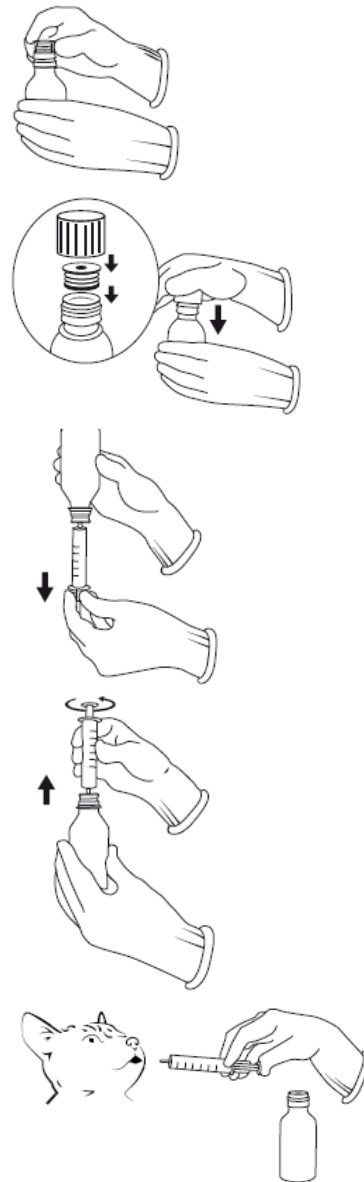
The suspension can be given using the 12 ml measuring syringe provided in the package. A syringe adapter (bung) is also provided in the package for insertion in the neck of the bottle before use.

9. Advice on correct administration

Impermeable gloves should be worn to avoid skin contact with the veterinary medicinal product.

Dosing procedure using the measuring syringe:

1. Estimate the body weight of the dog or cat accurately to ensure correct dosage. Refer overleaf for correct dosage amount.
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.



10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 18576/4000

Pack Size: 100 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Foran Healthcare,
Red Mills,
Goresbridge,
Kilkenny,
R95 EKH4,
Ireland
Tel.: +353 (0) 1 626 8058

Manufacturer responsible for batch release:

Thepenier Pharma & Cosmetics,
Route Départementale 912,
61400 Saint Langis les Mortagne,
France

17. Other information

Approved 20 August 2025

Gavin Hall