

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

### OUTER CARTON

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parazole Dog/Cat 100 mg/ml Oral Suspension  
Fenbendazole

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of fenbendazole.

#### 3. PHARMACEUTICAL FORM

Oral Suspension.

#### 4. PACKAGE SIZE

100 ml

#### 5. TARGET SPECIES

Dogs and Cats

#### 6. INDICATION(S)

Wormer for dogs & cats.

Effective Against:

Roundworms

Tapeworms

Hookworms

Lungworms

Roundworm eggs

For uses, dosage, administration, contraindications and warnings, see package leaflet.

#### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For uses, dosage, administration, contraindications and warnings, see package leaflet.

Method and route of administration:

Estimate body weight accurately before calculating the dosage.

Shake well before use.

Administer orally either directly into the dog or cat's mouth or alternatively 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.

### Dosage:

#### Routine treatment of adult dogs and cats:

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

#### 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 1ml 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.

#### Pregnant bitches:

1ml per 4kg body weight daily from day 40 of pregnancy continuously for approximately 25 days. This is equivalent to 25 mg Fenbendazole/kg body weight daily.

Read the package leaflet before use.

### **8. WITHDRAWAL PERIOD**

### **9. SPECIAL WARNING(S), IF NECESSARY**

Impermeable gloves should be worn to avoid contact with the product. Wash hands after use.

For uses, dosage, administration, contraindications and warnings, see package leaflet.

Read the package leaflet before use.

### **10. EXPIRY DATE**

EXP {month/year}:

Once opened, use / discard by \_\_\_\_\_

Shelf life after first opening the container: 6 months

### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

Dispose of waste material in accordance with local requirements.

### **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

IE Only: CAM

UK Only: AVM-GSL

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Foran Healthcare  
Red Mills  
Goresbridge  
Kilkenny  
R95 EKH4  
Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 18576/4000

**17. MANUFACTURER’S BATCH NUMBER**

BATCH NO:

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

### **BOTTLE LABEL**

#### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Parazole Dog/Cat 100 mg/ml Oral Suspension  
Fenbendazole

#### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains 100 mg of fenbendazole.

#### **3. PHARMACEUTICAL FORM**

Oral Suspension

#### **4. PACKAGE SIZE**

100 ml

#### **5. TARGET SPECIES**

Dogs and Cats

#### **6. INDICATION(S)**

Wormer for dogs & cats.

Effective Against:

Roundworms

Tapeworms

Hookworms

Lungworms

Roundworm eggs

#### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Method and route of administration:

Estimate body weight accurately before calculating the dosage.  
Shake well before use.

Administer orally either directly into the dog or cat's mouth or alternatively 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.

Dosage:

Routine treatment of adult dogs and cats:

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

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 1ml 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.

Pregnant bitches:

1ml per 4kg body weight daily from day 40 of pregnancy continuously for approximately 25 days. This is equivalent to 25 mg Fenbendazole/kg body weight daily.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Impermeable gloves should be worn to avoid contact with the product. Wash hands after use.

For uses, dosage, administration, contraindications and warnings, see package leaflet.

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}:

Once opened, use / discard by \_\_\_\_\_

Shelf life after first opening the container: 6 months

**11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

Dispose of waste material in accordance with local requirements.

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

IE Only: CAM

**UK Only:** AVM-GSL

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Foran Healthcare  
Red Mills  
Goresbridge  
Kilkenny  
R95 EKH4  
Ireland

**16. MARKETING AUTHORISATION NUMBER**

Vm 18576/4000

**17. MANUFACTURER’S BATCH NUMBER**

BATCH NO:

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:  
PARAZOLE DOG/CAT 100 MG/ML ORAL SUSPENSION**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder

Foran Healthcare  
Red Mills  
Goresbridge  
Kilkenny  
R95 EKH4  
Ireland

Manufacturer responsible for batch release:

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Parazole Dog/Cat 100 mg/ml Oral Suspension  
Fenbendazole

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

A white to off-white suspension.

Each ml contains 100 mg of Fenbendazole and 2.5 mg of Methyl Parahydroxybenzoate as a preservative.

**4. INDICATION(S)**

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 case of hypersensitivity to the active substance or to any of the excipients.

**6. ADVERSE REACTIONS**

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

**7. TARGET SPECIES**

Dogs and cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

### Dosage

Routine treatment of adult dogs and cats:

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

See dosage chart below for examples:

	Body weight	Volume of Parazole
<b>Adult Cat</b>	2kg	2ml
	4kg	4ml
	6kg	6ml
<b>Small Dog</b>	3kg	3ml
	5kg	5ml
<b>Medium Dog</b>	15kg	15ml
	25kg	25ml
<b>Large Dog</b>	35kg	35ml
	40kg	40ml

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 1ml 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.

Pregnant bitches:

1ml per 4kg 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 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 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 PERIOD**

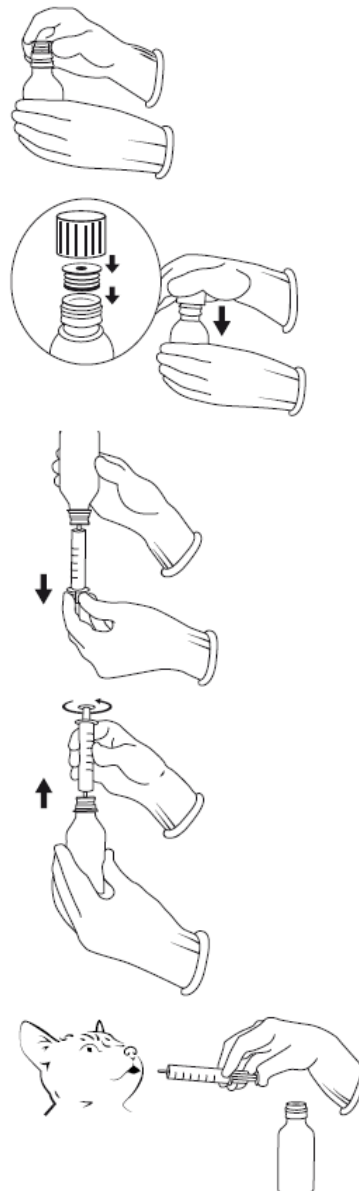
Not applicable.

**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 container: 6 months

**UK only:**

When the container is breached / opened for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

## **12. SPECIAL WARNING(S)**

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.

Special precautions for use in animals:

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.

Impermeable gloves should be worn to avoid skin contact with the 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 product is not mixed with other medicinal products.

Overdose (symptoms, emergency procedures, antidotes):

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.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **14. 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](http://www.gov.uk).

## 15. OTHER INFORMATION

For animal treatment only.

Pack Sizes: 100ml

### IE Only

VPA [To be completed nationally]

CAM

Companion Animal Medicine

### UK Only

Vm 18576/4000

AVM-GSL

Authorised Veterinary Medicine – General Sales List

Approved