Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Parazole 10% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Fenbendazole	100 mg
Excipients	
Methyl Parahydroxybenzoate	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 known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None known.

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:
Avoid 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:

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

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.

Estimate body weight accurately.

100 ml pack size only:
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.

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.

5.2 Pharmacokinetic properties

Fenbendazole is absorbed poorly and most of the drug is excreted unchanged in the faeces. The metabolites which have been identified are excreted in the urine and bile. Very little is excreted in the milk in cattle. The active and its metabolites are mainly found in the plasma and, over time, in liver.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

Polyethylene containers of 200 ml, 225 ml, 450 ml, 500 ml, 1 L, 2 L and 2.5 L size with tamper evident heat seal closures.

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.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ltd
2 Cherry Orchard Industrial Estate
Dublin 10

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10484/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1997

Date of last renewal: 9th January 2007

10 DATE OF REVISION OF THE TEXT

February 2016