

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Worming Granules for Cats and Kittens, 222 mg/g.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substance</u>	<u>mg/g</u>
Fenbendazole	222

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules
Free flowing, white to greyish white, granular powder.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

Treatment of immature and mature stages of common roundworms of domestic cats.
The product also has an ovicidal effect on nematode eggs.

4.3 Contra-indications

None known.

4.4 Special warnings for each target species

Seek the advice of a veterinary surgeon for the treatment of pregnant cats.

4.5 Special precautions for use

- (i) Special precautions for use in animals

None.

- (ii) Special precautions to be taken by the person administering the medicinal product to animals

Direct contact with the skin should be kept to a minimum.
Avoid the inhalation of dust.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only, sprinkled onto food or by mouth.

For the routine treatment of adult cats, a dosage of 100 mg Fenbendazole per kg bodyweight is recommended.

Very small or unweaned kittens up to 12 weeks of age should be treated with a suitable product.

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

Benzimidazoles have a wide safety margin.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics

ATCvet code: QP52AC13

5.1 Pharmacodynamic properties

Fenbendazole is a member of the benzimidazole family of anthelmintics. Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells, preventing the absorption of glucose. Parasites are gradually starved to death.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone K30
Sodium lauryl sulphate

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a dry place.
Add to feed immediately before administration.
Discard any remaining medicated feed.

6.5 Nature and composition of immediate packaging

1 g of product contained in a paper/low density polyethylene/foil/low density polyethylene sachet.

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

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

Sinclair Animal and Household Care Ltd.
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

8. MARKETING AUTHORISATION NUMBER

Vm 16516/4020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08 January 2002/08 January 2007

10. DATE OF REVISION OF THE TEXT

September 2009