

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Ear Drops, Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyrethrum Pale Extract (25%)	0.40% w/v
(equivalent to Pyrethrins)	0.10% w/v
Piperonyl Butoxide	1.00% w/v

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution.

Clear, very pale yellow liquid with odour characteristic of Terpineol.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats over 12 weeks of age.

4.2 Indications for use, specifying the target species

Treatment of ear mite (*Otodectes cynotis*) infestation in dogs and cats over 12 weeks of age.

4.3 Contra-Indications

Do not use on puppies and kittens under 12 weeks of age.

4.4 Special warnings for each target species

If signs of ear problems persist or worsen, consult a Veterinary Surgeon immediately.

4.5 i) Special precautions for use in animals

For external use only.

Avoid contact with the eyes.

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

Avoid contact with eyes.

If eye contact occurs, rinse with clean, fresh water. Seek medical advice if irritation persists. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

None stated.

4.8 Interaction with other medicinal products and other forms of interaction

None reported.

4.9 Amounts to be administered and administration route

Directions for use: for Dogs , Cats, Puppies and Kittens over 12 weeks of age:
The drops should be gently warmed to body heat e.g. by holding bottle in hand for a few minutes before use. Shake bottle, hold above ear and very gently squeeze in 3-6 drops according to size of animal as shown below.

Cats and very small Dogs - 3 drops	Small Dogs - 4 drops
Medium Dogs - 5 drops	Large Dogs - 6 drops

Hold head on one side for 15-20 seconds to allow drops to penetrate ear canal, massaging gently the base of the ear before allowing animal to shake its head. Use daily for 7 days. Always treat both ears, whether infested or not. To ensure complete clearance of mites, a second course of treatment as above may be given one week after the end of the first treatment.

NOTE: Never probe inside the ears as this can cause pain and injury. Any discharge on the outer surface of the ears may be wiped away gently with cotton wool.

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

None stated.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals, Antiparasitics

ATC Vet code: QS02QA

5.1 Pharmacodynamic properties

The plant Pyrethrum is a chrysanthemum; the powdered, dried flower heads contain active principles mainly in the form of pyrethrins. Pyrethrins have insecticidal activity producing both knock-down and mortality in a range of insects,

and low mammalian toxicity. Common names: Dalmatian insect powder and Persian insect powder.

Piperonyl butoxide acts as a synergist when combined with pyrethrin and prolongs its action.

5.2 Pharmacokinetic particulars

No other information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Terpineol
Industrial Methylated Spirits 74 OP
Propylene Glycol

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.
Protect from frost.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Pack Size: 15ml
Container: Round white LDPE unprinted
Plug: White one-drop
Cap: White polypropylene

Secondary packaging: Self-adhesive label and solid board carton.

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

Johnson's Veterinary Products Ltd
5 Reddicap Trading Estate
Sutton Coldfield
West Midlands
B75 7DF

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01759/4074

9. DATE OF FIRST AUTHORISATION

Date of first Authorisation: 14.02.02

10. DATE OF REVISION OF THE TEXT

February 2012