

## **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, Antiparascitics

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