

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar ear drops solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Ear Drops, solution.

4. PACKAGE SIZE

15ml

5. TARGET SPECIES

Dogs and Cats over 12 weeks of age.

6. INDICATION(S)

Beaphar ear drops soften wax, soothe irritation, assist healing and contain natural pyrethrum to kill ear mites (*Oteodectes cyonotis*) and are suitable for the treatment of common mite infestations which cause mild scratching or head shaking or dark, dry, waxy debris in one or both ears.

7. CONTRAINDICATIONS

The drops are not suitable for treating severe ear infestations – consult a veterinary surgeon immediately if there is a heavy strong smelling discharge or serious inflammation, swelling or pain with severe scratching, head shaking, or tilting.

8. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

9. WITHDRAWAL PERIOD

Not applicable.

10. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with eyes.

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

If signs of ear problems persist or worsen, consult a veterinary surgeon immediately.

11. EXPIRY DATE

12. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from frost & direct sunlight. Keep container in outer carton.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household refuse. **14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** [*Distribution category*]

AVM-GSL

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

Keep out of reach of children

16. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Johnson’s Veterinary Products Limited

5 Reddicap Trading Estate

Sutton Coldfield, West Midlands

B75 7DF. UK

17. MARKETING AUTHORISATION NUMBER(S)

Vm 01759/4074

18. MANUFACTURER’S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Manufactured by:

Sinclair Animal and Household Care, Ropery Road, Gainsborough, DN21 2QB

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Ear Drops solutions

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

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

4. PHARMACEUTICAL FORM

Ear Drops Solution

5. PACKAGE SIZE

15 ml

6. INDICATION(S)

Beaphar ear drops soften wax, soothe irritation, assist healing and contain natural pyrethrum to kill ear mites (*Oteodectes cyonotis*) and are suitable for the treatment of common mite infestations which cause mild scratching or head shaking or dark, dry, waxy debris in one or both ears.

7. CONTRAINDICATIONS

The drops are not suitable for treating severe ear infestations – consult a veterinary surgeon immediately if there is a heavy strong smelling discharge or serious inflammation, swelling or pain with severe scratching, head shaking, or tilting.

9. TARGET SPECIES

Dogs, cats, puppies and kittens over 12 weeks of age

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

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.

11. ADVICE ON CORRECT ADMINISTRATION

For external use only. Avoid contact with eyes

If signs of ear problems persist or worsen, consult a veterinary surgeon immediately.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from frost & direct sunlight. Keep container in outer carton.

14. SPECIAL WARNING(S)<

Avoid contact with eyes.

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

15. EXPIRY DATE

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

Dispose of empty packaging and any remaining product in the household refuse.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

AVM- GSL

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

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01759/4074

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

ManA 16576

Approved: 26/07/2017

