

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Veterinary Ear Drops Solution for Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

<u>Qualitative composition</u>	<u>Quantitative composition</u>
Chlorbutanol hemihydrate	1.1% w/w
Phenoxyethanol	1.0% w/w

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution.
A clear, colourless, slightly viscous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

For the treatment of ear irritation and otitis externa caused or complicated by infection in cats and dogs.

4.3 Contraindications

Do not use if the eardrum is perforated.

4.4 Special warnings for each target species

If symptoms persist or appear, consult your veterinary surgeon.

4.5 Special precautions for use

i) Special precautions for use in animals

For external use only

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

Avoid contact with skin and eyes.

In the event of accidental skin exposure, wash the affected area with soap and water.

In the event of accidental eye exposure, flush eye thoroughly with running water.

If irritation persists, seek medical advice showing the product label to the doctor.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not contraindicated during pregnancy but should not be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

For topical administration

Any excess exudates, hair or debris should be carefully removed before application. Squeeze 3 or 4 drops into the affected ear once a day holding the animal's head still for a few moments to allow thorough penetration of the solution. Repeat daily until condition clears, usually 4 or 5 days. If necessary continue use to clear any waxy debris. After healing has taken place, check ears at regular intervals for any sign of reinfection and treat as necessary.

Do not exceed the recommended dosage. Use each container for only one animal. Discontinue treatment if hypersensitivity occurs.

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

Not applicable

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals; Antiinfectives, combinations

ATCvet code: QS02AA30

5.1 Pharmacodynamic properties

Chlorbutol has anti-fungal and anti-bacterial properties. Phenoxyethanol is a bactericide particularly effective against *Pseudomonas aeruginosa* and can be used topically in the treatment of bacterial infections. The formulation represents complete solution of the 2 active ingredients in a non-aqueous base of propylene glycol with a pine perfume for consumer acceptability, which also helps to indicate which ear has been treated. Propylene glycol is commonly employed as the base in aural products and possesses anti-fungal and ear wax solvent properties. Clinical trials have demonstrated that Otodex Veterinary Ear Drops are effective in the treatment of the ear mite *Otodectes cyonotis* in the dog and cat although none of the components of Otodex Veterinary Ear Drops has recognised acaricidal activity.

5.2 Pharmacokinetic particulars

Not stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Pine DH30 1988 Fragrance

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary medicinal products as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C
Do not use if neck seal is broken at time of purchase.

6.5 Nature and composition of immediate packaging

14ml white low density polyethylene bottle with an LDPE dropper insert and high density polyethylene cap (screw fit) with tamper-evident seal.

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

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

Petlife International Limited
Unit 2, Cavendish Road
Bury St Edmunds
Suffolk
IP33 3TE

8. MARKETING AUTHORISATION NUMBER(S)

Vm 13240/4001

9. DATE OF FIRST AUTHORISATION

4th October 1995

10. DATE OF REVISION OF THE TEXT

August 2008