

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Skin Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)

Chlorocresol	0.500% w/w
Phenoxyethanol (constituent of Phenonip preservative, see below)	0.720% w/w
Zinc Oxide	9.000% w/w
Lidocaine Hydrochloride	0.050% w/w

Excipients

Quinoline Yellow dye	0.005% w/w
Phenonip (preservative) (comprising 0.720% w/w phenoxyethanol (above) and 0.28%w/w mixed hydroxybenzoate esters)	1.000% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.
Pale yellow, oily cream with the odour of fern for topical application.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and Dogs.

4.2 Indications for use, specifying the target species

As an aid in the treatment of eczema, sore spots, abrasions and minor burns.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

For external use only. Use sparingly in cases where large areas of skin are damaged or affected.

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

Wash hands after use. In the event of accidental eye contact wash immediately with copious amounts of water. If the skin or eye irritation persists – seek medical attention showing the product label to the doctor.

4.6 Adverse reactions (frequency and seriousness)

Cats are particularly susceptible to CNS effect, of phenols, including vomiting, in coordination, depression and coma. When Chlorocresol has been absorbed systemically treatment should be symptomatic.

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

Contact with non-ionic surfactants may reduce the activity of certain phenols.

4.9 Amounts to be administered and administration route

Clean wound, carefully remove over-lying hair from affected parts and lightly apply the cream at night and in the morning.

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

See 4.6 above.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Phenol and derivatives, combinations

ATCvet code: QD08AE99

5.1. Pharmacodynamic properties

Chlorocresol is a powerful phenolic disinfectant with lower toxicity than phenol but known CNS stimulant properties in cats, which also aids in the presentation of the product. Phenoxyethanol is a bactericide particularly effective against *Pseudomonas aeruginosa* and can be used topically in the treatment of bacterial infections. Zinc oxide is applied externally as a mild astringent for the skin, as a soothing and protective application in eczema, and as a protective to slight excoriations. Lidocaine hydrochloride is a local anaesthetic which has an analgesic function in the formulation.

5.2 Pharmacokinetic particulars

Not stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenonip - consists of: 2-Phenoxyethanol >60%
Methyl-4-hydroxybenzoate 15-30%
Ethyl-4-hydroxybenzoate <5%
Butyl-4-hydroxybenzoate <5%
Isobutyl-4-hydroxybenzoate <5%
Propyl-4-hydroxybenzoate <5%

Quinoline yellow
Liquid paraffin
White beeswax
White soft paraffin
Hard paraffin
Wool alcohols
Borax
Sorbitan monoisostearate
Fern DH192
Water potable

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C. Do not use if tube seal is broken when purchased.

6.5 Nature and composition of immediate packaging

35g Containers; collapsible aluminium epoxy phenol internally lacquered tube; 11mm membrane nozzle fitted with a white polypropylene screw fit cap.

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 13240/4000

9. DATE OF FIRST AUTHORISATION

04 October 1995

10. DATE OF REVISION OF THE TEXT

August 2008