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Requires a veterinarian's prescription
For veterinary use only

1. POSATEX Veterinary

Ear drops suspension for dogs

2. COMPOSITION:

Active substances:

Orbifloxacin 8.5 mg/ml

Mometasone furoate (as monohydrate) 0.9 mg/ml

Posaconazole 0.9 mg/ml

Therapeutic group: A combination of a corticosteroid, fluoroquinolones and azole antifungal agent.

3. PHARMACEUTICAL FORM:

Ear drops suspension for dogs.

Homogenous, white to off-white viscous suspension.

4. CLINICAL PARTICULARS:

4.1 Target species: Dogs

4.2 Indication:

Treatment of acute otitis externa and acute exacerbation of recurrent otitis externa, associated with bacteria susceptible to orbifloxacin and fungi susceptible to posaconazole, in particular, the *Malassezia pachydermatis* yeast.

4.3 Contraindications:

Do not use if the eardrum is perforated.

Do not use in case of sensitivity to any of the ingredients of the medicine, to corticosteroids, to other azole antifungal medicines, or to fluoroquinolones.

Do not use during part of or the whole pregnancy.

Do not use in breeding animals.

Do not use in dogs under 4 months of age.

4.4 Special warnings:

Fungal or bacterial otitis is usually secondary in nature. The primary cause of inflammation must be identified and treated.

4.5 Precautions for use:

Precautions for use in animals:

Heavy reliance on a single class of antibiotic may cause resistance of the bacterial population; exercise caution when using fluoroquinolones and reserve them for treating clinical conditions that have not responded or are not expected to respond to other types of antibiotics.

Use of this product should be based on bacterial susceptibility testing and bacterial cultures, and/or other appropriate diagnostic tests.

Quinolone class veterinary medicinal products have been associated with cartilage erosions in weight-bearing joints and other forms of arthropathy in immature animals. Therefore, do not use in animals under 4 months of age.

Prolonged and intensive use of topical corticosteroid-containing preparations is known to cause local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing. See section 4.10.

Before applying the veterinary medicinal product, the **external auditory canal** must be examined thoroughly to ensure that the eardrum is not torn or perforated, in order to avoid the risk of transmission of the infection to the middle ear and to prevent damage to the cochlear and vestibular apparatus.

Precautions to be taken by the person treating animals with the veterinary medicinal product:

Wash hands thoroughly after applying the veterinary medicinal product.

Avoid skin contact.

In case of accidental exposure, thoroughly rinse the exposed area with clean water.

Keep out of the reach of children.

4.6 Adverse reactions:

Mild erythematous lesions may appear. Use of this preparation may be associated with hearing impairment, usually temporary, and primarily in geriatric dogs.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

4.7 Use during pregnancy and lactation:

The safety of this veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy

Do not use this preparation during part of the pregnancy or the whole pregnancy.

Lactation

Use of this veterinary medicinal product is not recommended during lactation.

Laboratory studies in puppies have shown evidence of arthropathy after systemic administration of orbifloxacin. Fluoroquinolones are known to cross the placenta and also to pass into milk.

Fertility

Studies to determine the effect of orbifloxacin on fertility in dogs have not been conducted.

Do not use in breeding animals.

4.8 Drug interactions:

No data available.

4.9 Dosage and administration route:

For auricular use:

Each drop of the preparation contains:

267 µg orbifloxacin, 27 µg mometasone furoate, 27 µg posaconazole.

The external ear canal should be meticulously cleaned and dried before treatment. Excess hair in the treated area should be removed.

After applying the preparation to the ear, the base of the ear should be massaged gently and briefly to allow the medicine to penetrate the lower part of the ear canal.

Shake well before use.

Dosage:

For dogs weighing **less than 2 kg**: apply 2 drops to the ear once a day.

For dogs weighing **between 2-15 kg**: apply 4 drops to the ear once a day.

For dogs weighing **15 kg or more**: apply 8 drops to the ear once a day.

Treatment should be administered for seven consecutive days.

4.10 Overdose (symptoms, emergency intervention, antidote):

Administration of the recommended dosage (4 drops per ear), 5 times daily for 21 consecutive days to dogs weighing between 7.6-11.4 kg caused a slight decrease in serum cortisol concentration after ACTH administration in an ACTH stimulation test. Discontinuation of treatment will result in a complete return to normal adrenal response.

5. PHARMACEUTICAL PARTICULARS:

5.1 LIST OF EXIPIENTS:

Lauric acid

Mineral oil/Paraffin liquid

Plasticised hydrocarbon gel ointment base (Plastibase 50 W)

5.2 Incompatibilities:

Not known. Studies with a range of ear cleaner preparations have shown no chemical incompatibility.

5.3 Shelf life:

Shelf life of the veterinary medicinal product in its original package: 2 years.

Shelf life after opening the package containing 8.8 ml: 7 days.

Shelf life after opening the package containing 17.5 ml or 35.1 ml: 28 days.

5.4 Storage instructions:

Store at a temperature below 25°C. Store in the original bottle.

5.5 Packaging:

White HDPE bottle with a white LDPE cap, provided with a white or transparent applicator. Bottles containing 8.8 ml, 17.5 ml, and 35.1 ml. Not all sizes may be marketed.

5.6 Handling empty packages:

Any unused veterinary medicinal product or waste materials derived from use of a veterinary medicinal product should be disposed of as toxic waste. Do not discard via the wastewater.

Manufacturer:

Vet Pharma Friesoythe GmbH, Sedelsbergerstr 26169 Friesoythe, Germany

License holder: Intervet Israel Ltd., Neve Ne'em Industrial Zone, Hod Hasharon 45240.