TERRA-CORTRIL®
Eye/Ear Suspension

VETERINARY MEDICINE

SCHEDULING STATUS:
Schedule 4.

PROPRIETARY NAME (AND DOSAGE FORM):
Terra-Cortril Eye/Ear Suspension.

COMPOSITION:
Terra-Cortril Eye/Ear Suspension with Polymyxin B Sulphate contains 5 mg of hydrocortisone acetate, 10 mg of oxytetracycline as the hydrochloride and 10 000 units of Polymyxin B Sulphate (equivalent to 1 mg of Polymyxin B standard) in each ml of a controlled viscous gel-like base.

PHARMACOLOGICAL CLASSIFICATION:
C 14.3 Combinations (anti-infectives with corticosteroids).

PHARMACOLOGICAL ACTION:
Oxytetracycline is a product of the metabolism of Streptomyces rimosus and is one of the family of tetracycline antibiotics. Oxytetracycline is primarily bacteriostatic and is thought to exert its antimicrobial effect by the inhibition of protein synthesis. It is active against a wide range of gram-negative and gram-positive organisms. The drugs in the tetracycline class have closely similar antimicrobial spectra, and cross-resistance among them is common.
Polymyxin B sulphate is one of a group of related antibiotics derived from Bacillus polymyx. Polymyxin B sulphate is rapidly bacteriocidal exclusively against gram-negative organisms. It is particularly effective against Pseudomonas aeruginosa (B. pyocyaneus) and Koch-Weeks bacillus, frequently found in local infections of the eye and ear and also against Aerobacter aerogenes, klebsiella pneumonia, Haemophilus influenzae, Escherichia coli, etc. The terramycin-polymyxin combination constitutes a particularly active antimicrobial association of two active antibiotics, one broad-spectrum and the other bactericidal against gram-negatives for the effective treatment of most local infections. Polymyxin B is particularly effective against Pseudomonas species, especially in combination with oxytetracycline as these two antibiotics act synergistically. Bacterial resistance to polymyxin B is infrequent and there is no cross-resistance between polymyxin B and oxytetracycline. This sterile suspension, which possesses simultaneously the advantages of an aqueous solution as well as an ointment, is ideal for use in conditions where topical, non-systemic action is desired. The concentration of hydrocortisone acetate supplied is ample for inflammatory reactions of the eye or ear resulting from allergy, infection or trauma. Concomitantly, the Terramycin present will prevent or overcome superficial infections due to Terramycin sensitive organisms. Terra-Cortril Eye/Ear Suspension with Polymyxin B-sulphate thus provides the combined effectiveness of an anti-allergic, anti-inflammatory hormone which controls excessive tissue reaction to infections, allergens and trauma, and the broad-spectrum activity of Terramycin against the primarily causative or secondary infecting organisms. Terramycin is clinically proven as the broad-spectrum antibiotic with the widest range of antimicrobial activity. Indications for Terramycin therapy include systemic and local infections caused by a wide variety of pathogenic organisms including both aerobic and anaerobic gram-positive and gram-negative bacteria; rickettsiae; spirochetes; large viruses; and certain protozoa. Terramycin is also used successfully in prophylaxis against infection associated with surgery or after trauma.

INDICATIONS:
Terra-Cortril Eye/Ear Suspension with Polymyxin B sulphate is recommended for the treatment of eye and ear conditions in which topical hydrocortisone is indicated, and for eye and ear conditions in which infection due to Terramycin and/or polymyxin susceptible organisms exists.
Terra-Cortril Eye/Ear Suspension with Polymyxin B sulphate is recommended for infections of the external ear canal due to Terramycin sensitive organisms; especially where of mixed bacterial etiology, as well as for infections where etiology remains obscure; also for diffuse otitis externa; and for localized lesions of various etiology which have become superinfected, including such lesions as eczema. In addition, Terra-Cortril Eye/Ear Suspension with Polymyxin B sulphate is recommended for treatment of excessive inflammatory reactions, pruritus; and chronic eczema.

CONTRA-INDICATIONS:
Do not administer where any corneal ulcer or erosion is present.

WARNINGS:
It is advisable to take particular care in cases where the infection may be complicated by the presence of organisms which are not controlled by the antibiotic content of this preparation. The topical effect of Terra-Cortril Eye/Ear Suspension with Polymyxin B Sulphate should be reinforced by systemic administration of Terramycin when it is noted that the eye/ear infection is deepseated or spreading. Care must be taken not to contaminate the nozzle of the tube with exudate from an infected site.

DOSAGE AND DIRECTIONS FOR USE:
Eye Affection: Instill one or two drops of Terra-Cortril Eye/Ear Suspension with Polymyxin B sulphate into the affected eye three times daily. Ear Affection: For the treatment of an affection of the external ear canal, it is recommended that 2 to 4 drops be instilled three times daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
None.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
The treatment of overdosage is symptomatic and supportive.

CONDITIONS OF REGISTRATION:
Advertising to the professions only.

IDENTIFICATION:
A yellow suspension.

PRESENTATION:
Terra-Cortril Eye/Ear Suspension with Polymyxin B Sulphate is supplied in 5 ml tubes.

STORAGE INSTRUCTIONS:
Store below 30°C. Keep out of reach of children and uninformed persons.

REFERENCE NUMBER:
83/505 (Act 101/1965)

APPLICANT:
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