

TRITOP®



Pharmacia & Upjohn

brand of neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride topical ointment

For Use in Animals Only

For topical ear and skin use in dogs, cats and horses

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

TRITOP Topical Ointment (neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment) contains in each gram the potent anti-inflammatory agent isoflupredone acetate 1 mg (0.1%); the antibiotic neomycin sulfate, 5 mg (0.5%) (equivalent to 3.5 mg neomycin); and the topical anesthetic tetracaine hydrochloride, 5 mg (0.5%). This combination is well suited for the treatment or adjunctive therapy of many ear and skin conditions, as well as a dressing for superficial wounds occurring in dogs, cats and horses. Its action is specific as to anti-inflammatory, bactericidal, and anesthetic properties.

ISOFLUPREDONE ACETATE

It has been reported by research workers that isoflupredone acetate is 14 times as potent as hydrocortisone as an anti-inflammatory steroid as measured by the cotton pellet implantation assay.

Isoflupredone acetate markedly inhibits inflammatory reaction through its controlling influence on connective tissue and vascular components. Topically applied isoflupredone acetate is rapidly effective. In otitis externa, wounds of the concha, ulcerations of the ear flaps, and irritated lesions of the skin, the inflammatory response may also be effectively inhibited by isoflupredone acetate. Chronic conditions respond more slowly and relapses are more frequent.

NEOMYCIN

Neomycin is an antibiotic substance derived from cultures of the soil organism *Streptomyces fradiae*. Its antimicrobial range includes both gram-positive and gram-negative organisms commonly responsible for or associated with otic infections, such as staphylococci, streptococci, *Escherichia coli*, *Aerobacter aerogenes*, and many strains of *Proteus* and *Pseudomonas* organisms. It is not active against fungi. Neomycin is unusually nontoxic for epithelial cells in tissue culture and is nonirritating in therapeutic concentrations. The presence of neomycin in TRITOP® Topical Ointment affords control of infections caused by neomycin susceptible organisms.

TETRACAINE

Tetracaine hydrochloride is a topical anesthetic agent that is more potent than either procaine or cocaine in comparable concentrations and has greater ability than procaine to penetrate mucous membranes. The duration of anesthetic action of tetracaine exceeds that produced by either butacaine or phenacaine.

Many investigators have demonstrated that local anesthesia plays a significant part in the promotion of healing, especially where pain is a prominent factor. It is believed that trauma stimulates local pain receptors, which results in reflex vasodilation, edema, tenderness, and muscular spasm.

If the reflex is abolished through use of a local anesthetic such as tetracaine, amelioration of these tissue changes that interfere with healing is favored. The local anesthetic action of tetracaine has proved to be of great value in alleviating the pain reflex in painful skin and ear conditions.

ADVANTAGES OF TRITOP OINTMENT

1. Potent anti-inflammatory effect of isoflupredone acetate.
2. Broad-spectrum bactericidal effect of neomycin.
3. Rapid anesthetic effect of tetracaine.
4. Prompt relief of symptoms.
5. Reduces further self-inflicted trauma.
6. Ease of application.

INDICATIONS

TRITOP Topical Ointment is indicated as treatment or adjunctive therapy of certain ear and skin conditions in dogs, cats and horses caused by or associated with neomycin susceptible organisms and/or allergy. In addition, it is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for post surgical application where reduction of pain and inflammatory response is deemed desirable.

TRITOP Topical Ointment is useful in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post surgical therapy in the horse, cat, and dog.

TRITOP Topical Ointment may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

WARNINGS

Not for human use.

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

PRECAUTIONS

Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact. If hearing or vestibular dysfunction is noted during the course of treatment discontinue use of TRITOP Topical Ointment.

Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of non-susceptible organisms or to prolonged use of antibiotic-containing preparations resulting in over-growth of non-susceptible organisms, particularly *Monilia*. Thus, if improvement is not noted within two or three days, or if redness, irritation, or swelling persists or increases, the diagnosis should be redetermined and appropriate therapeutic measures initiated.

Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to TRITOP Topical Ointment (neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment). If such signs are noted, therapy with TRITOP Topical Ointment should be stopped.

ADMINISTRATION

In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal may be applied one to three times daily. When used on the skin or mucous membranes, cleanse the affected area, apply a small amount of the ointment and spread or rub in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response. Limit treatment to the period when local anesthesia is essential to control self-inflicted trauma.

HOW SUPPLIED

TRITOP Topical Ointment is available in 10 gram tubes with a special applicator tip.

STORAGE

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

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