QUADRITOP™ OINTMENT

Rx

Butler Schein™ Animal Health

ANTI-INFLAMMATORY, ANTIPRURITIC, ANTIFUNGAL, AND ANTI-BACTERIAL

For the local therapy in a variety of cutaneous disorders of cats and dogs.

NADA 140-810, Approved by FDA

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

Quadritop Ointment is a combination of nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide in a nonirritating vehicle, a polyethylene and mineral oil gel base.

Each mL contains:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Nystatin</td>
<td>100,000 units</td>
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<tr>
<td>Neomycin sulfate (equivalent to neomycin base)</td>
<td>2.5 mg</td>
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<tr>
<td>Thiostrepton</td>
<td>2,500 units</td>
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<tr>
<td>Triamcinolone acetonide</td>
<td>1.0 mg</td>
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Quadritop Ointment is supplied in tubes of 1/4 fl. oz. (7.5 mL), 1/2 fl. oz. (15 mL), and 1 fl. oz. (30 mL), each with an elongated tip for easy application and in dispensing bottles of 8 fl. oz. (240 mL). The preparation is intended for local therapy in a variety of cutaneous disorders of cats and dogs; it is especially useful in disorders caused, complicated or threatened by bacterial and/or candidal (monilial) infections.

ACTIONS: By virtue of its four active ingredients, the ointment provides four therapeutic effects including anti-inflammatory, antipruritic, antifungal and antibacterial. Triamcinolone acetonide is a synthetic...
corticosteroid providing rapid and prolonged symptomatic relief upon topical administration. Inflammation, edema and pruritus subside and lesions are permitted to heal. Nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous infection caused by Candida albicans (monilia).

Nystatin is fungistatic *in vitro* against a variety of yeast and yeast-like fungi including many fungi pathogenic to animals. Activity is not exhibited against bacteria.

Thiostrepton has activity against gram-positive organisms, including many which are resistant to other antibiotics, neomycin exerts antimicrobial action against a wide range of gram-positive and gram-negative bacterial. Together they provide comprehensive therapy against organisms responsible for most superficial bacterial infections.

**INDICATIONS:**

Quadritop Ointment is useful in the treatment of acute and chronic otitis of varied etiologies, in interdigital cysts in cats and dogs, and in anal gland infections in dogs.

The preparation is also indicated in the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (Candida albicans) infections.

It is also indicated in eczematous dermatitis, contact dermatitis, and seborrheic dermatitis, and for use as an adjunct in the treatment of dermatitis due to parasitic infection.

**WARNING:** 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.

Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in the offspring.

In dogs, other congenital anomalies have resulted including deformed forelegs, phocomelia and anasarca.

**PRECAUTIONS:** Quadritop Ointment is not intended for the treatment of deep abscesses or deep-seated infections such as inflammation of the lymphatic vessels. Parenteral antibiotic therapy is indicated in these infections.

Quadritop Ointment (nystatin-neomycin sulfate-thiostrepton-triamcinolone acetonide ointment) has been well-tolerated. Cutaneous reactions attributable to its use have been rare. The occurrence of systemic reaction is rarely a problem with topical administration.

There is evidence that corticosteroids can be absorbed after topical application and cause systemic effects. Therefore, an animal receiving Quadritop Ointment therapy should be observed closely for signs such as polydipsia, polyuria, and increased weight gain. Quadritop Ointment is not generally recommended for the treatment of deep or puncture wounds, or serious burns.

Sensitivity to neomycin may occur. If redness, irritation or swelling persists or increases, discontinue use. Do not use if pus is present since the drug may allow the infection to spread. Keep out of the reach of children.

Avoid ingestion. Oral or parental use of corticosteroids (depending upon the dose, the duration of use, and the specific steroid) may result in the inhibition of endogenous steroid production following drug withdrawal.
SIDE EFFECTS: SAP and SGPT (ALT) enzyme elevations, polydipsia and polyuria, vomiting, and diarrhea (occasionally bloody) have been observed following the parenteral or systemic use of synthetic corticosteroids in dogs.

Cushing's syndrome has been reported in association with prolonged or repeated steroid therapy in dogs. Temporary hearing loss has been reported in conjunction with treatment of otitis with products containing corticosteroids. However, regression usually occurs following withdrawal of the drug. If hearing dysfunction is noted during the course of treatment with Quadritop Ointment, discontinue its use.

CAUTION: Before instilling any medication into the ear, examine the external ear canal thoroughly so that the tympanic membrane is not ruptured, avoiding the possibility of transmitting an infection into 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 the use of Quadritop Ointment.

DOSAGE AND ADMINISTRATION: The frequency of administration depends upon the severity of the condition.

For mild inflammations, the application may range from once a day to once a week.

For severe conditions Quadritop Ointment may be applied two to three times a day, if necessary. The frequency of the treatment may be decreased as improvement occurs.

Wear gloves during the administration of the ointment or wash hands immediately after the application.

OTITIS: Clean the ear canal of impacted cerumen. Inspect the canal and remove any foreign bodies such as grass awns, ticks, etc. Instill three to five drops of Quadritop Ointment. Preliminary use of a local anesthetic such as Proparacaine Hydrochloride Ophthalmic Solution may be advisable.

INFECTED ANAL GLANDS, CYSTIC AREAS, ETC: Drain the gland or cyst and then fill it with Quadritop Ointment.

OTHER DERMATOLOGIC DISORDERS: Clean the affected areas, removing any encrusted discharge or exudate. Apply thiostrepton-traimcinolone acetonide ointment sparingly in a thin film.

STORAGE: 240 mL bottle: Do not store above 86°F. 7.5 mL, 15 mL and 30 mL tubes: Store at room temperature and avoid excessive heat (104°F).

PRESENTATION: Quadritop Ointment is supplied in the following sizes: 7.5 mL tube, 7.5 mL tube x 144 units, 15 mL tube, 15 mL tube x 72 units, 30 mL tube, 240 mL tube applicator bottle.

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