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## PANOLOG® OINTMENT



Fort Dodge

## NYSTATIN-NEOMYCIN SULFATE-THIOSTREPTON-TRIAMCINOLONE ACETONIDE OINTMENT USP

FOR USE IN DOGS AND CATS ONLY

NADA 12-258, Approved by FDA

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

### DESCRIPTION

Panolog Ointment (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Ointment USP) combines nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide in a non-irritating, protective vehicle, a Plasticized Hydrocarbon Gel (polyethylene and mineral oil gel base).

Each mL contains:

|  |               |
|--|---------------|
| Nystatin                                     | 100,000 units |
| Neomycin sulfate equivalent to neomycin base | 2.5 mg        |
| Thiostrepton                                 | 2,500 units   |
| Triamcinolone acetonide                      | 1.0 mg        |

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 (monilia) infection.

## **ACTIONS**

By virtue of its four active ingredients, Panolog Ointment provides four basic therapeutic effects; anti-inflammatory, antipruritic, antifungal and antibacterial. Triamcinolone acetonide is a potent synthetic corticosteroid providing rapid and prolonged symptomatic relief on topical administration. Inflammation, edema and pruritus promptly subside and lesions are permitted to heal. Nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous infections 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. No appreciable activity is exhibited against bacteria. Thiostrepton has a high order of 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 bacteria. Together they provide comprehensive therapy against those organisms responsible for most superficial bacterial infections.

## **INDICATIONS**

Panolog Ointment is particularly 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 of value in eczematous dermatitis, contact dermatitis and seborrheic dermatitis; and as an adjunct in the treatment of dermatitis due to parasitic infestation.

## **WARNINGS**

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**

Panolog Ointment (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Ointment USP) 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.

Panolog Ointment has been extremely well tolerated. Cutaneous reactions attributable to its use have been extremely rare. The occurrence of systemic reactions is rarely a problem with topical administration. There is some evidence that corticosteroids can be absorbed after topical application and cause systemic effects. Therefore, an animal receiving Panolog Ointment therapy should be observed closely for signs such as polydipsia, polyuria and increased weight gain.

Panolog 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 this and all medications out of the reach of children.

Avoid ingestion. Oral or parenteral use of corticosteroids, depending on dose, duration and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal.

## **SIDE EFFECTS**

SAP and SGPT (ALT) enzyme elevations, polydipsia and polyuria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs.

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

## **CAUTION**

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 Panolog Ointment.

## **DOSAGE AND ADMINISTRATION**

Frequency of administration is dependent on the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions Panolog Ointment may be applied as often as two to three times daily, if necessary. Frequency of treatment may be decreased as improvement occurs.

*Otitis:* Clean ear canal of impacted cerumen. Inspect canal and remove any foreign bodies such as grass awns, ticks, etc. Instill three to five drops of Panolog Ointment.

*Infected anal glands, cystic areas, etc.:* Drain gland or cyst and then fill with Panolog Ointment.

*Other dermatologic disorders:* Clean affected areas, removing any encrusted discharge or exudate. Apply Panolog Ointment sparingly in a thin film.

## **HOW SUPPLIED**

Panolog 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.

Do not store above 86°F (30°C).

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|                   | NDC          |
|-------------------|--------------|
| 7.5 mL tube       | 53501-581-19 |
| 7.5 mL tube x 144 | 53501-581-78 |
| 15 mL tubes       | 53501-581-17 |
| 15 mL tube x 72   |              |
| 30 mL tubes       | 53501-581-28 |

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