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## NEO-PREDEF<sup>®</sup> WITH TETRACAINE POWDER



Pharmacia & Upjohn

NDC 0009-0584-01

**brand of neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride topical powder**

**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

NEO-PREDEF with Tetracaine Powder contains in each gram neomycin sulfate, 5 mg (equivalent to 3.5 mg neomycin); isoflupredone acetate, 1 mg; tetracaine hydrochloride, 5 mg; myristyl-gamma-picolinium chloride, 0.2 mg; also lactose hydrous. Because of the prompt, potent, and specific actions of the individual components, this combination is well suited for the treatment of certain ear and skin conditions occurring in dogs, cats and horses.

### ADVANTAGES OF NEO-PREDEF WITH TETRACAINE

1. Highly potent anti-inflammatory effect of isoflupredone acetate.
2. Wide-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.
7. Adherent to moist surfaces.

### **ISOFLUPREDONE ACETATE**

Isoflupredone acetate markedly inhibits inflammatory reaction through its controlling influence on connective tissue and vascular components. Topically applied isoflupredone acetate is usually 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 NEO-PREDEF with Tetracaine Powder affords control of neomycin-sensitive organisms.

### **TETRACAINE**

Tetracaine hydrochloride is a topical anesthetic agent that is more potent than either procaine or cocaine in comparable concentration. 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.

### **MYRISTYL-GAMMA-PICOLINIUM CHLORIDE**

Myristyl-gamma-picolinium Chloride is highly germicidal, nonirritating and relatively nontoxic. In solution it reduces surface tension (a surfactant), possesses detergent and emulsifying actions, and exhibits properties which favor the penetration and wetting of tissue surfaces. The drug is effective against a wide range of organisms, its active ingredient killing in ten minutes *Staphylococcus aureus* in dilutions up to 1:85,000 at 37 degrees Centigrade; *E. typhosa* in dilutions up to 1:140,000; *Esch. coli* in dilutions up to 1:40,000, and *S. dysenteriae* in dilutions up to 1:80,000.

Myristyl-gamma-picolinium Chloride has been used, per se, for preoperative disinfection of the skin, for application to superficial injuries, for irrigating deep wounds, and for application to infections and wounds of mucous membranes.

## **INDICATIONS**

NEO-PREDEF with Tetracaine Powder is indicated in the 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. NEO-PREDEF with Tetracaine Powder may be used as a dusting powder following amputation of tails, claws, and dew-claws; following ear trimming and castrating; and following such surgical procedure as ovariohysterectomies.

Applied superficially, it has been used successfully in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in the dog, and as a dusting powder to various minor cuts, lacerations, and abrasions in the horse, cat and dog.

## **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 NEO-PREDEF with Tetracaine Powder.

Incomplete response or exacerbation of corticosteroid-response lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible 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.

## **APPLICATION**

After cleansing the affected area, NEO-PREDEF with Tetracaine Powder is applied by compressing the sides of the container with short, sharp squeezes. In most instances a single daily application will be sufficient; however, it may be applied one to three times daily, as required.

## **HOW SUPPLIED**

NEO-PREDEF with Tetracaine Powder is available in 15 gram plastic insufflator bottles. Because of the hygroscopic properties of neomycin sulfate, **this bottle should be stored in a dry place**. The cap should be replaced when the bottle is not in use. The puffer bottle has been designed to permit dusting when held in any position. Protecting the outlet from moisture will aid in assuring proper function; therefore, **the tip should not be allowed to come in contact with moist membranes or weeping surfaces**.

## **STORAGE**

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

**NADA #15-433**

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Revised August 2005

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**NAC No.:** 10490382