

# **NEO-PREDEF WITH TETRACAINE- neomycin sulfate, isoflupredone acetate, and tetracaine hydrochloride powder**

**Zoetis Inc.**

-----

## **Neo-Predef<sup>®</sup> with Tetracaine**

### **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. Do not use in horses intended for human consumption.

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. This 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).

Distributed by:  
Zoetis Inc.  
Kalamazoo, MI 49007

Revised March 2013  
1471000  
PAA034872

## **PRINCIPAL DISPLAY PANEL - 15 g Bottle Carton**

12-15 gram bottles  
Sold in unbroken packages of 12 only

**Neo-Predef®**  
With Tetracaine Powder

**neomycin sulfate, isoflupredone acetate, tetracaine HCl powder**

For Topical Use  
**For Use in Animals Only**

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

12-15 gram bottles  
Sold in unbroken packages of 12 only

**Neo-Predef®**  
With Tetracaine Powder

**neomycin sulfate, isoflupredone acetate, tetracaine HCl powder**

For Topical Use  
**For Use In Animals Only**  
**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

FPO: LPC  
0009-0584-01 6

Distributed by:  
Zoetis Inc.  
Kalamazoo, MI 49007

**Warnings:**  
Not for human use. Do not use in horses intended for human consumption. 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. Store in a dry place at controlled room temperature 20° to 25°C (68° to 77°F).

FPO: 128 (10 mil)  
PAA034871

1471000  
PAA034871

Distributed by:  
Zoetis Inc.  
Kalamazoo, MI 49007

## NEO-PREDEF WITH TETRACAINE

neomycin sulfate, isoflupredone acetate, and tetracaine hydrochloride powder

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:54771-1584	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)		NEOMYCIN	5 mg in 1 g	
ISOFLUPREDONE ACETATE (UNII: 55P9TUL75S) (ISOFLUPREDONE - UNII:HYS0B45Z2S)		ISOFLUPREDONE ACETATE	1 mg in 1 g	
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)		TETRACAINE HYDROCHLORIDE	5 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54771-1584-1	15 g in 1 BOTTLE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NADA	NADA015433	01/13/1965		

**Labeler** - Zoetis Inc. (828851555)

Revised: 12/2017

Zoetis Inc.