# DUAL ACTION CREAMneomycinsulfate,polymyxinbsulfate,pramoxinehcl cream Trifecta Pharmaceutical USA LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

#### **Dual Action Cream**

#### **DRUG FACTS**

## **Active Ingredient**

Neomycin 3.5mg

## **Purpose**

First Aid Antibiotic

# **Active Ingredient**

Polymyxin B 10,000 Units

# **Purpose**

First Aid Antibiotic

# **Active Ingredient**

Pramoxine HCL 10mg

# Purpose

External Analgesic

#### Uses

First Aid to help prevent infection in minor cuts, scrapes and burns.

# Warnings

# For external use only. Do not use:

• If you are allergic to any of the ingredients

- in the eyes
- over large areas of the body

#### Ask a Doctor before Use

Ask Doctor before use if you have:

- Deep or puncture wounds
- Animal bites
- Serious burns

## Stop Use and ask a Doctor if:

- Condition persists or gets worse
- You need to use longer than 1 week
- A rash or other allergic reaction develops

## Keep out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away

#### **Directions**

- Clean the affected area and dry thoroughly
- Apply a small amount of this product (an amount equal to the surface area of the tip
  of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

# Questions

For Questions please call 1 888 296 9067

#### Other Information

- To Open: Unscrew cap, pull tab to remove foil seal
- Store at 20° to 25°C (68° to 77°F)
- See carton or tube crimp for lot number and expiration date

# **Inactive Ingredient:**

Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl Sterate, Light Mineral Oil, Petrolatum, Polyoxyethylene Lauryl Ether, Purified Water, Sodium Lauryl Sulfate.

# Distributed By

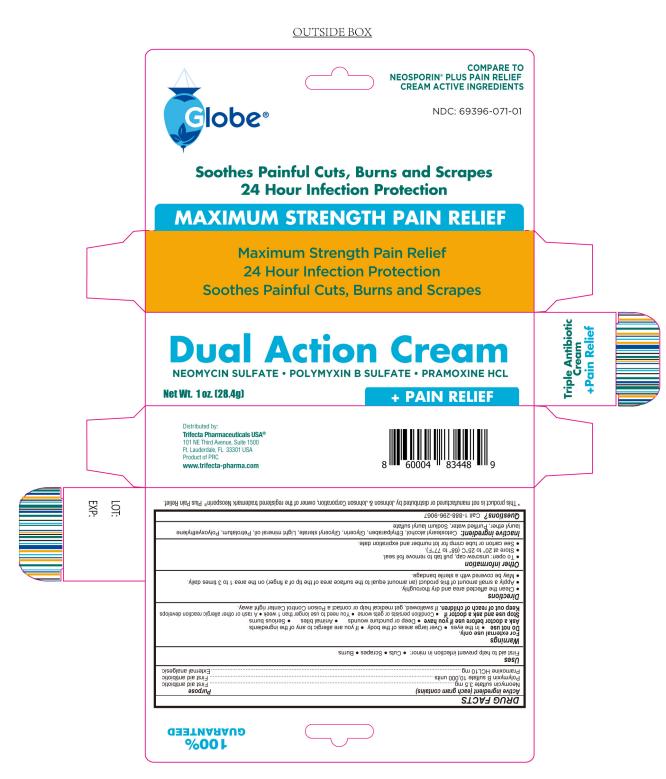
**T**rifecta Pharmaceuticals USA 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL. 33301

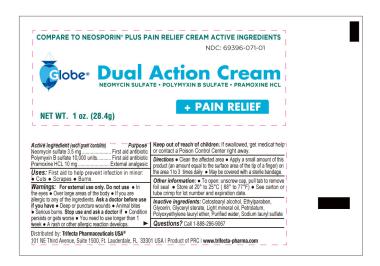
www.trifecta-pharma.com

Product of PRC

This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Neosporin Plus Pain Relief

# **Packaging**





## **DUAL ACTION CREAM**

neomycinsulfate,polymyxinbsulfate,pramoxinehcl cream

Proc	luct	Inform	nation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69396-071

Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g			
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g			
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g			

Inactive Ingredients				
Ingredient Name	Strength			
PETROLATUM (UNII: 4T6H12BN9U)				
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)				
LAURETH-23 (UNII: N72LMW566G)				
ETHYLPARABEN (UNII: 14255EXE39)				
WATER (UNII: 059QF0KO0R)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
GLYCERIN (UNII: PDC6A3C0OX)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-071- 01	1 in 1 BOX	01/22/2021	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information					
Marketing End Date					
rt					

# Labeler - Trifecta Pharmaceutical USA LLC (079424163)

Revised: 1/2023 Trifecta Pharmaceutical USA LLC