

**DUAL ACTION CREAM-  
neomycin sulfate, polymyxin sulfate, pramoxine hcl 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.*

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**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**

Trifecta 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

OUTSIDE BOX



**COMPARE TO NEOSPORIN® PLUS PAIN RELIEF CREAM ACTIVE INGREDIENTS**

NDC: 69396-071-01

**Soothes Painful Cuts, Burns and Scrapes  
24 Hour Infection Protection**

**MAXIMUM STRENGTH PAIN RELIEF**

Maximum Strength Pain Relief  
24 Hour Infection Protection  
Soothes Painful Cuts, Burns and Scrapes

**Dual Action Cream**  
NEOMYCIN SULFATE • POLYMYXIN B SULFATE • PRAMOXINE HCL

Net Wt. 1 oz. (28.4g) **+ PAIN RELIEF**

Distributed by:  
**Trifecta Pharmaceuticals USA®**  
101 NE Third Avenue, Suite 1500  
Ft. Lauderdale, FL 33301 USA  
Product of PRC  
www.trifecta-pharma.com



8 60004 83448 6

**Triple Antibiotic Cream  
+ Pain Relief**

LOT:  
EXP:

**100% GUARANTEED**

**DRUG FACTS**

**Active ingredient (each gram contains)**  
Neomycin sulfate 2.5 mg ..... First aid antibiotic  
Polymyxin B sulfate 10,000 units ..... First aid antibiotic  
Pramoxine HCL 10 mg ..... External analgesic

**Uses**  
First aid to help prevent infection in minor: • Cuts • Scrapes • Burns

**Warnings**  
For external use only.  
Do not use: • In the eyes. • Over large areas of the body. • If you are allergic to any of the ingredients  
**Ask a 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.

**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:** Cetostryl alcohol, Ethylparaben, Glycyrrhizic acid, Light mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Purified water, Sodium lauryl sulfate

**Questions?** Call 1-888-296-9067

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INNER TUBE

COMPARE TO NEOSPORIN<sup>®</sup> PLUS PAIN RELIEF CREAM ACTIVE INGREDIENTS  
NDC: 69396-071-01



## Dual Action Cream

NEOMYCIN SULFATE • POLYMYXIN B SULFATE • PRAMOXINE HCL

**+ PAIN RELIEF**

**NET WT. 1 oz. (28.4g)**

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<p><b>Active ingredient (each gram contains)</b></p> <p>Neomycin sulfate 3.5 mg ..... First aid antibiotic          Polymyxin B sulfate 10,000 units ..... First aid antibiotic          Pramoxine HCL 10 mg ..... External analgesic</p> <p><b>Uses:</b> First aid to help prevent infection in minor:          • Cuts • Scrapes • Burns</p> <p><b>Warnings:</b> For external use only. Do not use • in the eyes • Over large areas of the body • If you are allergic to any of the ingredients. Ask a 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</p> <p style="font-size: xx-small;">Distributed by: <b>Trifecta Pharmaceuticals USA<sup>®</sup></b>          101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA   Product of PRC   <a href="http://www.trifecta-pharma.com">www.trifecta-pharma.com</a></p>	<p><b>Purpose:</b></p> <p>First aid antibiotic          First aid antibiotic          External analgesic</p> <p><b>Directions:</b> Clean the affected area • 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.</p> <p><b>Other information:</b> • 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.</p> <p><b>Inactive ingredients:</b> Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl stearate, Light mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Purified water, Sodium lauryl sulfate.</p> <p><b>Questions?</b> Call 1-800-296-9067</p>	<p><b>Keep out of reach of children:</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>
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## DUAL ACTION CREAM

neomycinsulfate,polymyxinbsulfate,pramoxinehcl cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-071
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NEOMYCIN SULFATE</b> (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>LAURETH-23</b> (UNII: N72LMW566G)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LIGHT MINERAL OIL</b> (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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	01/06/2021	

**Labeler** - Trifecta Pharmaceutical USA LLC (079424163)

Revised: 1/2023

Trifecta Pharmaceutical USA LLC