

ATOPALM FIRST AID TRIPLE ANTIBIOTIC PROTECTION MOISTURIZING AND PAIN RELIEF - bacitracin zinc, neomycin sulfate, polymycin b sulfate, pramoxine hcl ointment
Neopharm Co., Ltd.

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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Active Ingredients (each gram contains)

Bacitracin Zinc 500 units

Neomycin Sulfate 3.5mg

Polymycin B Sulfate 10,000 units

Pramoxine HCl 10mg

Purpose

First Aid Antibiotic
Topical Analgesic

Uses

First aid to help prevent infection and for the temporary relief of pain and discomfort of minor cuts, scrapes, burns.

Warnings

For external use only

Do not use

- if you are allergic to any of the ingredients
- in or near the eyes
- longer than 1 week
- over large areas of the body

Ask a doctor before use

- on deep or puncture wounds, animal bites or serious burns

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days
- condition clears up and occurs again within a few days

- 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

Adults and children 2 years of age and older

- clean the affected area and dry thoroughly
- apply a small 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

Children under 2 yrs. of age

- Consult a doctor.

Other Information

- store at 68° – 77°F (20° – 25°C)
- see carton flap or tube crimp for lot number and expiration date

Inactive Ingredients

PETROLATUM, LIGHT MINERAL OIL, STEARIC ACID, CHOLESTEROL, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHMIDE MEA.

Questions or information call toll free:

Call 1-855-ATOPALM



First Aid Triple Antibiotic Pain Relieving Ointment

Maximum Strength without a prescription

ATOPALM™

FIRST AID TRIPLE ANTIBIOTIC PROTECTION

In a Moisturizing Pain Relieving Ointment Based on US Patented **M L E** Technology

MOISTURIZING OINTMENT + PAIN RELIEF

First Aid to help prevent infection and for the temporary relief of pain and discomfort of minor cuts, scrapes and burns.

ATOPALM™

ATOPALM

Moisturizing First Aid Triple Antibiotic Protection + Pain Relief

First Aid Antibiotic Ointment + Pain Relief

ATOPALM™

FIRST AID TRIPLE ANTIBIOTIC PROTECTION

In a Moisturizing Pain Relieving Ointment Based on US Patented MLE Technology

MOISTURIZING OINTMENT + PAIN RELIEF



Net Wt. 1 oz / 28.3 g

Bacitracin Zinc ■ Neomycin Sulfate
Polymyxin B Sulfate ■ Pramoxine Hydrochloride

ATOPALM™

FIRST AID TRIPLE ANTIBIOTIC PROTECTION

In a Moisturizing Pain Relieving Ointment Based on

US Patented MLE Technology

MOISTURIZING OINTMENT + PAIN RELIEF



75734

US Patent # US 6,221,371 B1
Distributed by Neopharm USA, 1 Oyster Bay Drive, Rumson, NJ 07750
Made in Korea

Drug Facts (continued)
Directions Adults and children 2 years of age and older ■ clean affected area and dry thoroughly ■ apply a small 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. Children under 2 years of age ■ consult a doctor.
Inactive Ingredients PETROLATUM, LIGHT MINERAL OIL, STEARIC ACID, CHOLESTEROL, MYRISTYL PALMITOYL OXOSTEARAMIDE/BRACHAMIDE MEA.
Other Information ■ store at 68°-77°F (20°-25°C) ■ see carton flap or tube crimp for lot number and expiration date
Questions or information call toll free: 1-855-ATOPALM

Drug Facts
Active Ingredients (each gram contains) Bacitracin Zinc 500 units First Aid Antibiotic Neomycin Sulfate 3.5 mg First Aid Antibiotic Polymyxin B Sulfate 10,000 units First Aid Antibiotic Pramoxine HCl 10 mg Topical Analgesic
Uses First aid to help prevent infection and for the temporary relief of pain and discomfort of minor cuts ■ scrapes ■ burns
Warnings For external use only. Do not use ■ if allergic to any of the ingredients ■ in or near the eyes ■ longer than 1 week ■ over large areas of the body. Ask a doctor before use ■ on deep or puncture wounds, animal bites or serious burns. Stop use and ask a doctor if ■ condition gets worse ■ condition persists for more than 7 days ■ condition clears up and occurs again within a few days ■ 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.

without a prescription

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FIRST AID TRIPLE ANTIBIOTIC OINTMENT + PAIN RELIEF

First Aid Antibiotic – Pain Relieving Ointment
 Maximum Strength without a prescription

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MOISTURIZING OINTMENT + PAIN RELIEF

Net Wt. 1 oz / 28.3 g

Bacitracin Zinc ■ Neomycin Sulfate
 Polymyxin B Sulfate ■ Pramoxine Hydrochloride

Active Ingredients (in each gram) Bacitracin Zinc 500 units, Neomycin Sulfate 3.5 mg, Polymyxin B Sulfate 10,000 units, Pramoxine HCl 10 mg

Uses: First aid to help prevent infection and for the temporary relief of pain and discomfort in minor cuts ■ scrapes ■ burns.

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Questions or information call toll free: 1-855 ATOPALM

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea #75734

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bacitracin zinc, neomycin sulfate, polymyxin b sulfate, pramoxine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0238
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [iU] in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0238-1	1 in 1 CARTON		
1		28.3 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 final	part333B	08/08/2012	

Labeler - Neopharm Co., Ltd. (965502912)**Establishment**

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture(51141-0238)

Revised: 6/2015

Neopharm Co., Ltd.