TRIPLEANTIBIOTICOINTMENTANDPAINRELIEF- bacitracin,neomycin,polymxin, pramoxine ointment
Trifecta Pharmaceuticals USA

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.

Triple Antibiotic Ointment + Pain Relief

DRUG FACTS

Active Ingredient

Bacitracin 500 Units

Purpose

First Aid Antibiotic

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
- Burns

Warnings

For external use only. Do not use:

- In eyes
- Over large areas of the body
- If you are allergic to any of the ingredients

Ask a Doctor before Use

Ask Doctor before use if you have:

- Deep or puncture wouns
- 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
- 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:

Light mineral oil, Petrolatum

Questions?

Call 1-888-296-9067

Distributed By:

Trifecta Pharmaceuticals USA ®

101 NE Third Avenue, Suite 1500

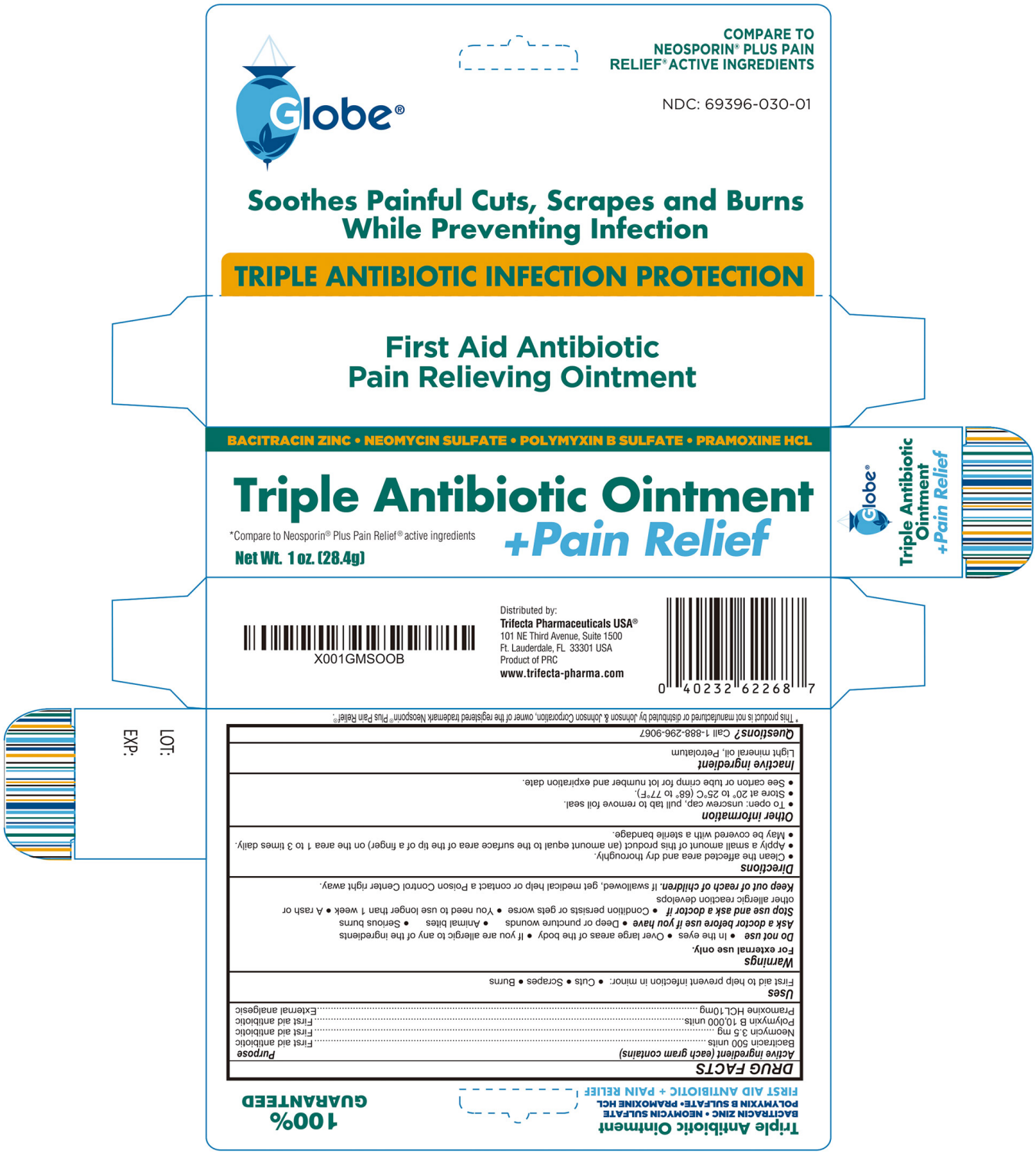
Fort Lauderdale, FL. 33301 USA

Product of PRC

www.trifecta-pharma.com

Packaging

OUTER BOX



INNER TUBE

Active ingredient (each gram contains) | Purpose
Bacitracin 500 units ..... First aid antibiotic
Neomycin 3.5 mg ..... First aid antibiotic
Polymyxin B 10,000 units ..... First aid antibiotic
Pramoxine HCL 10mg ..... 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 ● 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: Light mineral oil, Petrolatum

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TRIPLEANTIBIOTICOINTMENTANDPAINRELIEF

bacitracin,neomycin,polymxin, pramoxine ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 100 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 100 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-030-01	1 in 1 BOX	07/20/2017	
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 final	part333B	07/20/2017	

Labeler - Trifecta Pharmaceuticals USA (079424163)