TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
Chain Drug Marketing Association Inc.

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.

Quality Choice Triple Antibiotic Ointment Plus Pain Relief

Active ingredients (each gram contains)

Bacitracin zinc 400 units

Neomycin sulfate 3.5 mg

Polymyxin B sulfate 5,000 units

Purpose

First aid antibiotic

Active Ingredient

Pramoxine HCL

Purpose

External Analgesic

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

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.

Inactive ingredient Mineral Oil,Petrolatum

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.

Other Information

Distributed by C.D.M.A., Inc.

43157 W 9 Mile Rd

Novi, MI 48375

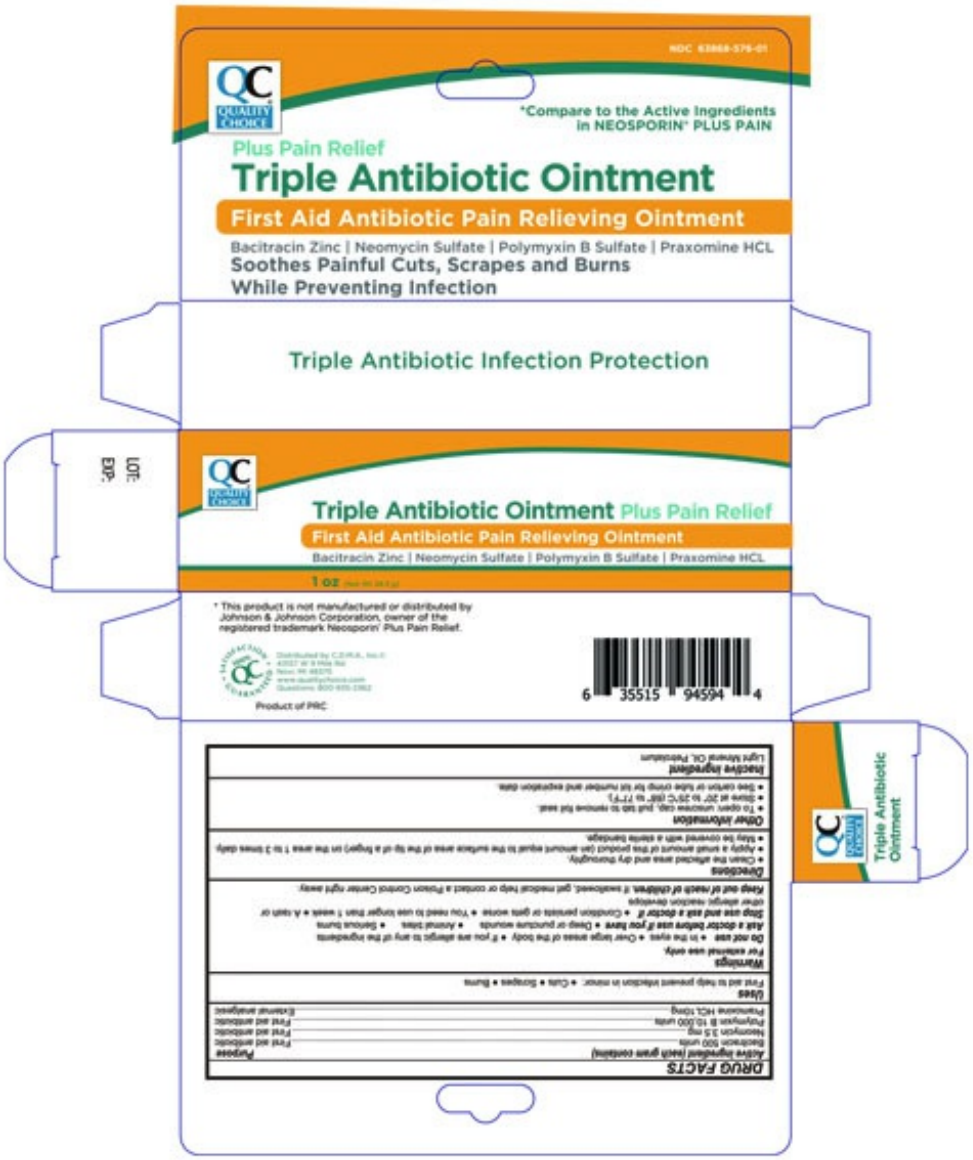
www.qualitychoice.com

questions: 800-935-2362

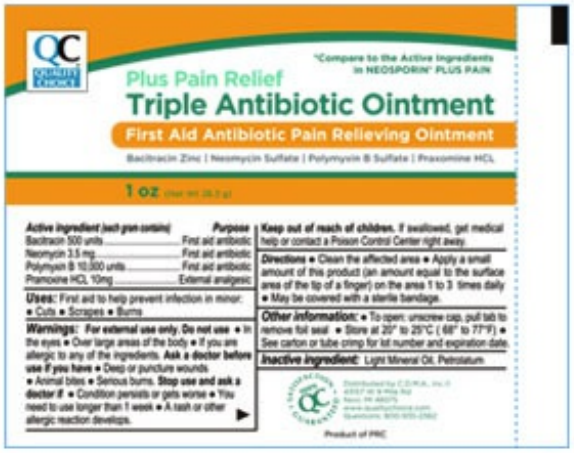
Product of PRC

Packaging

OUTER BOX



INNER TUBE



TRIPLE ANTIBIOTIC PLUS PAIN RELIEF

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-576
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] 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 [USP'U] in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-576-01	1 in 1 BOX	06/15/2020	
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	06/15/2020	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 5/2023 Chain Drug Marketing Association Inc.