

TRIPLE ANTIBIOTIC- neomycin and polymyxin b sulfates and bacitracin zinc ointment
Rebel Distributors Corp

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.

Fougera[®] Triple Antibiotic Ointment
(Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment USP)

Drug Facts

Active ingredients (in each gram)

Neomycin Sulfate (5 mg equivalent to 3.5 mg neomycin base)
Polymyxin B Sulfate (equal to 5,000 polymyxin B units)
Bacitracin Zinc (equal to 400 bacitracin units)

Purpose

Antibiotic
Antibiotic
Antibiotic

Uses

first aid to help prevent infection in

- minor cuts
- scopes
- bums

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 in case of deep or puncture wounds, animal bites or serious bums

When using this product do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- the condition persists or gets worse
- if 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

- do not use if seal is punctured or is not visible. To open, reverse cap to puncture seal
- store at room temperature
- see crimp of tube for Lot No. and Exp, date

Inactive ingredient white petrolatum

Questions or comments? call toll free 1-800-645-9833

PRINCIPAL DISPLAY PANEL



TRIPLE ANTIBIOTIC

neomycin and polymyxin b sulfates and bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-194(NDC:0168-0012)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin Zinc - UNII:89Y4M234ES)	Bacitracin Zinc	400 [USP.U] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:I16QD7X297)	Neomycin Sulfate	5 mg in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	5000 [USP.U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-194-15	1 in 1 CARTON		
1		15 g in 1 TUBE		
2	NDC:21695-194-28	1 in 1 CARTON		
2		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/06/2010	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp