

CVS HEALTH TRIPLE ANTIBIOTIC WITH PAIN RELIEF- bacitracin zinc, polymyxin b sulfate, neomycin sulfate and pramoxine hcl ointment

CVS Health

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.

Drug Facts

Active ingredients (In each gram)

Bacitracin 500

Neomycin 3.5 mg

Polymyxin B 10,000 units

Pramoxine HCL 10 mg

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Pain Relief

Uses

helps prevent infection in and temporarily relieves pain due to minor:

- cuts
- scrapes
- burns

Warnings

For external use only

Allergy alert:

- do not use if you are allergic to any of the ingredients

Do not use

- in or near the eyes
- on large areas of the body

Consult a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use longer than 1 week

Stop use and consult a doctor if

- condition persists or gets worse
- symptoms last for more than 7 days or clear up and come back within a few days
- a rash or other allergic reaction develops

Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center immediately.

Directions

- clean the affected area
- apply a small amount (equal to surface area of tip of finger) on the area 1 to 3 times daily.
- may be covered with a sterile bandage

Other information

- Store at a controlled room temperature 68°-77°F (20°-25°C)

Inactive ingredient

Petrolatum

Distributed by CVS Pharmacy 1-800-SHOP CVS

Principal Display Panel – Packet Label



CVS Health NDC 69842-161-10

Triple Antibiotic Ointment & Pain Relief Bacitracin Zinc • Neomycin Sulfate • Polymyxin-B Sulfate • Pramoxine HCL

First Aid Antibiotic/Pain relieving Ointment

NET WT. 0.03 oz. (0.9g)

Principal Display Panel – Carton Label



CVS Health NDC 69842-161-10

Triple Antibiotic & Pain Relief Ointment

Bacitracin Zinc • Neomycin Sulfate • Polymyxin-B Sulfate•Pramoxine HCL

First Aid Antibiotic /Pain relieving Ointment

24 packets

NET WT. 0.72 oz. (20.4g)

First Aid Treatment for Minor Cuts, Scrapes and Burns

CVS HEALTH TRIPLE ANTIBIOTIC WITH PAIN RELIEF			
bacitracin zinc, polymyxin b sulfate, neomycin sulfate and pramoxine hcl ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-161
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)		Bacitracin	500 [USPU] in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:12V707196K)		Polymyxin B	10000 [USPU]

Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:32V207590K)	Polymyxin B	in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:H6QD7X297)	Neomycin	3.5 mg 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-161-10	24 in 1 CARTON	04/28/2017	
1		0.9 g in 1 PACKET; 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	04/28/2017	

Labeler - CVS Health (062312574)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(69842-161)

Revised: 9/2017

CVS Health