PENTREXCILINA TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin, neomycin, polymyxin b, pramoxine ointment
OPMX LLC

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.

Pentrexcilina Triple Antibiotic

ACTIVE INGREDIENTS (IN EACH GRAM)

BACITRACIN ZINC 500 UNITS

NEOMYCIN SULFATE 5 MG (EQUIVALENT TO 3.5 MG NEOMYCIN)

POLYMYXIN B SULFATE 5000 UNITS

PRAMOXINE HYCHLORIDE 10 MG

PURPOSE

FIRST AID ANTIBIOTIC

PAIN RELIEVER

USES

- FIRST AID TO HELP PREVENT INFECTION IN
- MINOR CUTS
- SCRAPES
- BURNS

WARNINGS

For external use only.

DO NOT USE

- IN THE EYES
- IF YOU ARE ALLERGIC TO ANY OF THE INGREDIENTS
- OVER LARGE AREAS OF THE BODY
- LONGER THAN 1 WEEK UNLESS DIRECTED BY A DOCTOR

ASK A DOCTOR BEFORE USE IN CASE OF

- DEEP OR PUNCTURE WOUNDS
- ANIMAL BITES
- OR SERIOUS BURNS

Keep out of reach of children

- If swallowed get medical help or contact 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

INACTIVE INGREDIENTS

WHITE PETROLATUM

OTHER INFORMATION

- STORE AT 15° - 30°C (59°F - 86°F)
- AVOID EXCESSIVE HEAT AND HUMIDITY

Pentrexilina Triple Antibiotic

NDC 69729-616-61

PENTREXCILINA TRIPLE ANTIBIOTIC PLUS PAIN RELIEF

bacitracin, neomycin, polymyxin b, pramoxine ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-616
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	5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-616-61	1 in 1 BOX	09/05/2018	
1	NDC:69729-616-01	14 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	09/05/2018	

Labeler - OPMX LLC (029918743)

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