CUADRIDERMA- bacitracin zinc, polymyxin b sulfate, neomycin sulfate, and pramoxine hydrochloride ointment ProMex 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.

Cuadriderma®

Drug Facts

Active ingredients (in each gram)	Purpose
Bacitracin 500 units	First aid antibiotic
Neomycin 3.5 mg	First aid antibiotic
Polymyxin B 10,000 units	First aid antibiotic
Pramoxine hydrochloride 10 mg	Pain reliever

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 allergic to any of the ingredients

Do not use

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

Ask 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 ask a doctor if

- * condition lasts 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 occurs.

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

Directions

Adults and children 2 years and older:

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

Children under 2 years: ask a doctor

Other information

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

Inactive ingredient

Petrolatum

Questions Comments

1 (305) 653-2700

PRINCIPAL DISPLAY PANEL - 28.35 g Tube Carton

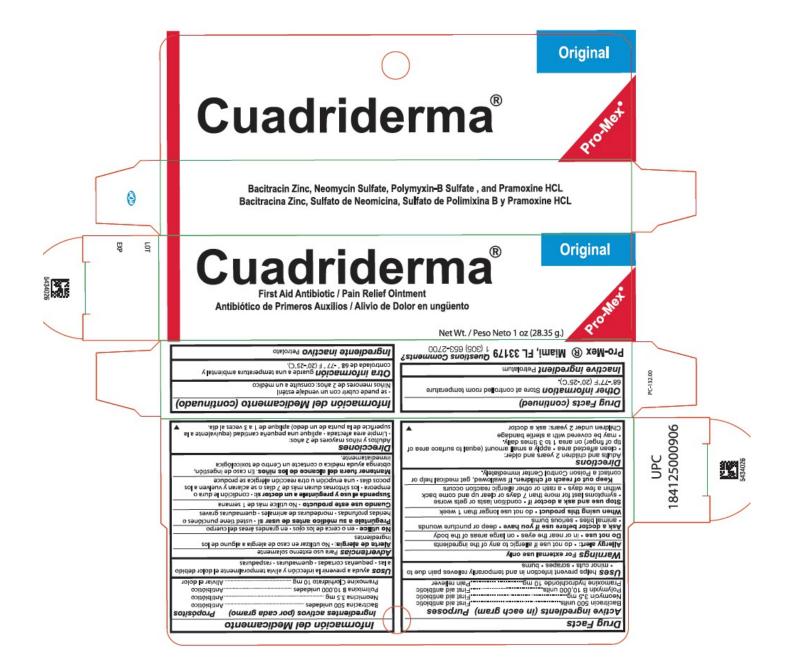
Original

Cuadriderma®

First Aid Antibiotic / Pain Relief Ointment

Net Wt. 1 oz (28.35 g.)

Pro-Mex®



CUADRIDERMA

bacitracin zinc, polymyxin b sulfate, neomycin sulfate, and pramoxine hydrochloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-1170
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
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B	10000 [iU] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:116QD7X297)	Neomycin	3.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE -	PRAMOXINE	10 mg in 1 g

UNII:068X84E056) HYDROCHLORIDE

Inactive Ingredients	
Ingredient Name	Strength
Petrolatum (UNII: 4T6H12BN9U)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58988- 1170-1	1 in 1 CARTON	05/31/2013	
1	28.35 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	05/31/2013	

Labeler - ProMex LLC (789974388)

Revised: 1/2022 ProMex LLC