# ANTIBIOTIC AND PAIN RELIEF MAXIMUM STRENGTH- bacitracin zinc neomycin sulfate polymyxin b sulfate pramoxine hcl ointment Kinray, 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.

Bacitracin Zinc, Neomycin Sulfate, Polymyxin B Sulfate, Pramoxine Hydrochloride

### ACTIVE INGREDIENTS

#### (in each gram)

Bacitracin zinc 500 units

Neomycin 3.5 mg

Polymyxin B sulfate 10,000 units

Pramoxine hydrochloride 10 mg

#### PURPOSES

First aid antibiotic/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 right away.

#### 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 a sterile bandage

Children under 2 years: ask a doctor

#### **INACTIVE INGREDIENT**

White petrolatum

# **QUESTIONS?**

1-800-432-8534 (select option #2) between 9 am and 4 pm EST, Monday-Friday.

Store at 59° - 86°F (15° - 30°C).

# PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

\*Compare to the active ingredients in Neosporin<sup>®</sup> + Pain Relief

Preferred plus ++++ Pharmacy

#### ANTIBIOTIC + PAIN RELIEF

MAXIMUM STRENGTH OINTMENT BACITRACIN ZINC – NEOMYCIN SULFATE - POLYMYXIN B SULFATE - PRAMOXINE HCl FIRST AID ANTIBIOTIC /PAIN RELIEVING OINTMENT NET WT 1 OZ (28 G) **INFECTION PROTECTION** FOR BURNS, CUTS & SCRAPES Maximum Strength Pain Relief Ointment

08230209A1 VC109276



#### ANTIBIOTIC AND PAIN RELIEF MAXIMUM STRENGTH

bacitracin zinc neomycin sulfate polymyxin b sulfate pramoxine hcl ointment					
Product Information					
Product Type	HUMAN OTC DRUG Item Cod		ode (Source)	e (Source) NDC:6377	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Str	<b>Basis of Strength</b>	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)			BACITRACIN ZIN	BACITRACIN ZINC	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)			NEOMYCIN	NEOMYCIN	
POLYMYXIN B SULFATE (UNII: 1 UNII:J2VZ07J96K)	POLYMYXIN B S	POLYMYXIN B SULFATE			
<b>PRAMO XINE HYDRO CHLO RIDE</b> (UNII: 88 AYB867L5) (PRAMO XINE - UNII:068 X84E056)			PRAMOXINE HYDROCHLORID	PRAMOXINE HYDROCHLORIDE	
Inactive Ingredients					
Ingredient Name				Strength	
PETROLATUM (UNII: 4T6 H12BN9 U)					
Packaging					
# Item Code	Package Description	Marketin	ng Start Date	Marketing End Date	
<b>1</b> NDC:63777-082-31 1 in 1	CARTON				
1 28 g	in 1 TUBE				
Marketing Information					
Marketing Category Applie	Application Number or Monograph Citation		Marketing Start 1	Date M	arketing End Date
OTC monograph final part333B	-	(			-

# Labeler - Kinray, Inc. (012574513)

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Kinray, Inc.