PROCOMYCIN- bacitracin, neomycin, polymyxin b and lidocain hydrochloride cream
Aidarex Pharmaceuticals 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.

Drug Facts

Active ingredients

Bacitracin 500 units

Neomycin 3.5.mg

Polymyxin B 10,000 units

Purpose

First Aid Antibiotic

Active ingredient

Lidocaine Hydrochloride 4%

Purpose

Local Anesthetic

Uses

- First aid to help prevent the infection in minor cuts, scrapes and burns
- For the temporary relief of pain or itching.

Warnings

For external use only.

Do not use

- in the eyes
- over large areas of the body
- if allergic to any of the ingredients
- longer than 1 week unless directed by a doctor.

Consult a doctor

- if under 2 years of age
- in case of deep cuts or puncture wounds, animal or human bites, or serious burns
- if pregnant or breast feeding.

Stop use and consult a doctor

- if the condition persists or worsens
- if symptoms persist for more than 7 days or clear up and occur again within a few days

- 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 for use

- Clean the affected area
- apply a small amount of this product (an amount equal to the surface area of the tip of the finger) on the area 3 times daily.
- may be covered with a sterile bandage
- store at controlled room temperature 15°-30° (59°-86°).

Inactive ingredients

acrylates/dimethicone coploymer, allantoin, aloe barbadensis (aloe vera) leaf juice, arachidyl alcohol, arachidyl glucoside, arnica montana flower extract, ascorbic acid (vitamin C), behenyl alcohol, beta-glucan, benzalkonium chloride, beta-glucan, butyrospermum parkii (shea) butter, C 12-15 alkyl benzoate, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, cyclopentasiloxane, dimethicone, dipalmitoyl hydroxyproline, glycerin, glycine soja (soybean) oil, helianthus annuus (sunflower) seed oil, hydrolyzed mytilus edulis byssus, methylparaben, panthenol, persea gratissima (avocado) oil, phenoxyethanol, polyglyceryl-6 distearate, propylparaben, sclerotium gum, tocopherol, water (aqua)

Manufactured in the USA for:

Physician's Science and Nature, Inc.

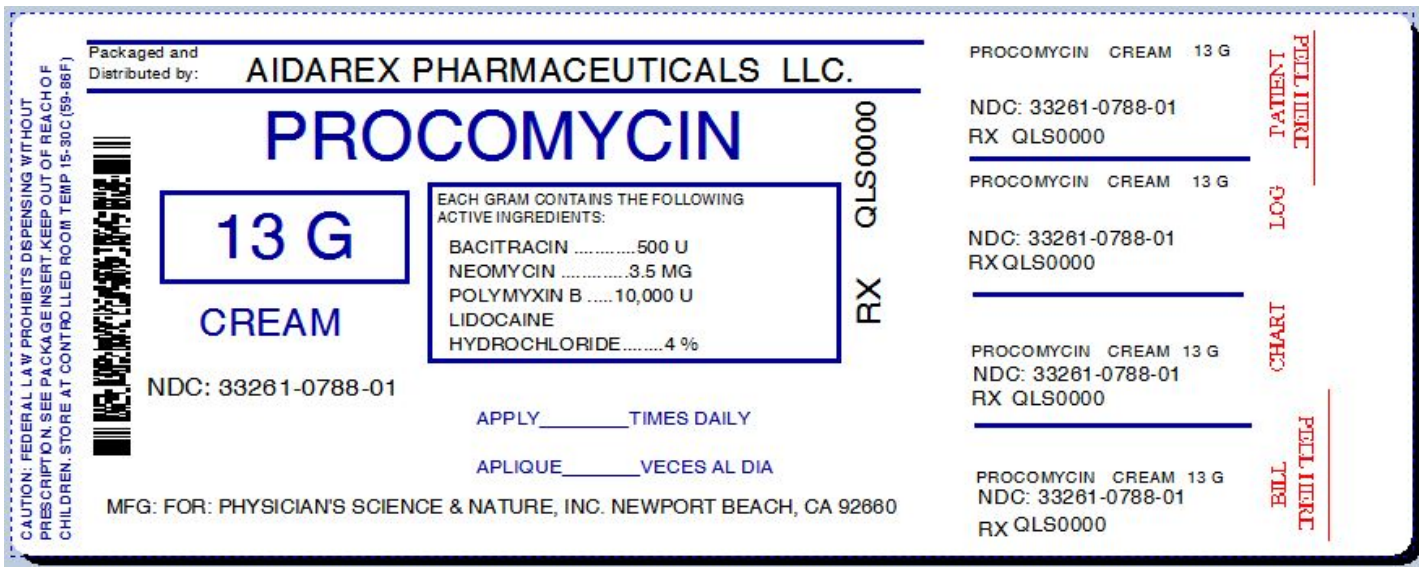
220 Newport Center Drive, 11-634,

Newport Beach, CA 92660

www.procomycin.com

Repackaged By:
Aidarex Pharmaceuticals, LLC.
Corona, CA 92880

Package/Label Principal Display Panel



PROCOMYCIN

bacitracin, neomycin, polymyxin b and lidocain hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33261-788(NDC:27495-010)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [iU] in 1 g
NEOMYCIN (UNII: I16QD7X297) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	0.0035 g in 1 g
POLYMYXIN B (UNII: J2VZ07J96K) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [iU] in 1 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.04 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
DOCOSANOL (UNII: 9G1OE216XY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN (UNII: L7HT8F1ZOD)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:33261-788-01	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/01/2010	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 1/2014 Aidarex Pharmaceuticals LLC