DG HEALTH MEDICATED ANTI-ITCH ANALGESIC- menthol, unspecified form and pramoxine hydrochloride cream
DOLGENCORP, 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.

DG™ Health Medicated Anti-Itch Cream
Topical Analgesic

Drug Facts

Active ingredients	*Purpose*
Menthol 1%	Anti-itch, pain relief
Pramoxine hydrochloride 1%	Anti-itch, pain relief

Use

For temporary relief of pain and itching associated with minor skin irritations, minor burns, minor cuts, sunburns, scrapes, insect bites, and rashes due to poison ivy, poison oak, or poison sumac

Warnings

For external use only.

Avoid contact with eyes and nose.

Not for prolonged use.

Do not use
- on large areas of the body

Stop use and ask a doctor if
- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness, irritation, swelling, or pain develops, persists, or increases

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions
- **adults and children 2 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 2 years of age:** ask a doctor

Other information
- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, carbomer, cetearyl alcohol, DMDM hydantoin, glycerin, polysorbate 60, propylene glycol, purified water, triethanolamine

Questions or comments?

888-309-9030

DISTRIBUTED BY OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

DG™| health

Compare to the active ingredients
of Gold Bond® Medicated
Anti-Itch Cream*

Medicated
Anti-Itch Cream
Menthol, Pramoxine Hydrochloride

NET WT 1 OZ (28 g)

DG HEALTH MEDICATED ANTI-ITCH ANALGESIC

menthol, unspecified form and pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-330
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	10 mg in 1 g
Pramoxine Hydrochloride (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-330-24	1 in 1 CARTON	01/02/2008	
1		28 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 not final	part347	01/02/2008	

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(55910-330)