

**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.*

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**DG™ Health Medicated Anti-Itch Cream**  
**Topical Analgesic**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Menthol 1%	Topical Analgesic
Pramoxine hydrochloride 1%	Topical Analgesic

**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 DOLGENCORP, LLC  
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

NDC 559 10-330-24  
Compare to the active ingredients  
of Gold Bond® Medicated  
Anti-Itch Cream\*

# Medicated Anti-Itch Cream

Menthol, Pramoxine Hydrochloride

- Soothing
- Enriched with Aloe
- Relieves pain & itch fast

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V01

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Medicated  
Anti-Itch  
Cream  
Menthol  
Pramoxine Hydrochloride

100%  
Satisfaction  
Guaranteed!  
(888) 309-9030

DISTRIBUTED BY DOLGENCORP, LLC  
100 MISSION RIDGE  
GOODLETTSVILLE, TN 37072  
MADE IN U.S.A.



\*This product is not manufactured by or distributed by Challeng, Inc., the distributor of Gold Bond® Medicated Anti-Itch Cream.

<b>Drug Facts</b>
<b>Active Ingredients</b> Menthol 1% Pramoxine hydrochloride 1% Topical Analgesic
<b>Purpose</b> Relieves Two Itch Relieving Ingredients
<b>Use</b> For temporary relief of pain and itching associated with minor skin irritations, minor burns, minor cuts, sunburns, scrapes, insect bites, and aches due to poison ivy, poison oak, or poison sumac
<b>Warnings</b> 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 7 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, cetylalcohol, DMDM hydantoin, glycerin, polyethylene glycol, purified water, triethanolamine Questions or comments? 888-309-9030

menthol, unspecified form and pramoxine hydrochloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:559 10-330
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:559 10-330-24	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(559 10-330)