

ANTI-ITCH- men-phor lotion
CARDINAL HEALTH

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.

Anti-Itch Lotion

Drug Facts

Active Ingredient Purpose

0.5% Camphor Anti-Infective, Anti-Pruritic

0.5% Menthol Anti-Pruritic

Intended Use

To provide temporary relief for dry
itching skin, sunburn, insect bites and pruritus

Directions

Apply two or three times daily, or as directed by your physician

Warnings

Avoid contact with eyes.If contact occurs, rinse eyes thoroughly with water.

If improvement does not occur, or condition worsens after regular use as directed,
discontinue use and consult a physician.

Do not use on children under two years of age.

Do not apply under compresses or bandages

Inactive Ingredients

Purified water, Carbopol, Cetearyl alcohol, Cetyl alcohol, DMDM hydantoin,
Fragrance, Glycol stearate, PEG-4 Dilaurate, PEG-40 Castor oil, Petrolatum,
Sodium cetearyl sulfate, Stearic acid, TEA

Keep out of reach of children

Apply two or three times daily

CM K

Leader Anti-Itch
FRONT

PMS 282

Leader Anti-Itch
BACK

Compare to
SARNA Lotion®
active ingredient*

STEROID FREE

Anti-Itch Lotion

Cools & Relieves Itching

Effective for:
Sunburn, Poison Ivy,
Poison Oak, Insect Bites



*Registered trademark of Stiefel Laboratories

7.5 FL OZ (222mL)

Drug Facts

Active Ingredient: **Purpose:**
0.5% Camphor Anti-Infective, Anti-Pruritic
0.5% Menthol Anti-Pruritic

Intended Use: To provide temporary relief for dry itching skin, sunburn, insect bites and pruritus.

Warnings:

For External Use Only

- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- If improvement does not occur, or condition worsens after regular use as directed, discontinue use and consult a physician.
- Do not use on children under two years of age.
- Do not apply under compresses or bandages.

Keep out of reach of children

Directions:

- Apply two or three times daily, or as directed by your physician.

Inactive Ingredients:

Purified Water, Carbopol, Cetearyl Alcohol, Cetyl Alcohol, DMDM Hydantoin, Fragrance, Glycol Stearate, PEG-4 Dilaurate, PEG-40 Castor Oil, Petrolatum, Sodium Cetearyl Sulfate, Stearic Acid, TEA



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DUBLIN, OHIO 43017
CIN 4217709
www.myleader.com
1-800-200-6313

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

ANTI-ITCH

men-phor lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-683(NDC:54162-550)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.5 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PEG-4 DILAURATE (UNII: KCR71CW036)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHYLAMINE (UNII: VOU728O6AY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-683-82	222 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/16/2012	

Labeler - CARDINAL HEALTH (097537435)

Registrant - GERITREX CORP (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX CORP		112796248	manufacture(37205-683)

Revised: 11/2012

CARDINAL HEALTH