ANTI ITCH MAXIMUM RELIEF- pramoxine hydrochloride and menthol cream
Natureplex 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.

Anti-Itch Cream
Maximum Relief

Drug Facts

Active ingredients	***Purpose***
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 old and older:** apply to affected area not more than 3 to 4 times daily
- **children under 2 years old:** 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?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 42.5 g Tube Box

Natureplex™

MAXIMUM RELIEF

Medicated
Anti-Itch Cream

NET WT. 1.5 Oz. (42.5g)

ANTI ITCH MAXIMUM RELIEF

pramoxine hydrochloride and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67234-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 g
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	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:67234-008-01	1 in 1 BOX	01/02/2008	
1		42 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 - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-008)

Revised: 11/2017 Natureplex LLC