GNP ANTI ITCH- camphor, menthol lotion AMERISOURCEBERGEN DRUG CORPORATION

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.

GNP Original Anti-Itch Lotion

Active Ingredients

Camphor 0.5%	. External
analgesic	
Menthol 0.5%	External
analgesic	

Uses

temporary relieves pain and itching due to:

insect bites

minor burns

sunburn

minor skin irritations

minor cuts

scrapes

rashes due to poison ivy, poison oak, and poison sumac

Warning

For external use only

Ask doctor before use

on chicken pox

on measles

when using this product

do not get into eyes

Stop Use and ask doctor if

condition worsens

symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Purpose

Directions

to open, squeeze cap tightly and turn pump counter-clockwise adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily children under 2 years: ask a doctor

Other information

store at 20 °C to 25 °C (68 °F to 77 °F)

Inactive ingredients

carbomer 940, cetyl alcohol, DMDM hydantoin, fragrance, glyceryl stearate, isopropyl myristate, PEG-40 stearate, PEG-100 stearate, purified water, sodium hydroxide, stearic acid, white petrolatum.

Principal Display Panel

Original Formula Anti-Itch Lotion

Camphor 0.5%

Menthol 0.5%

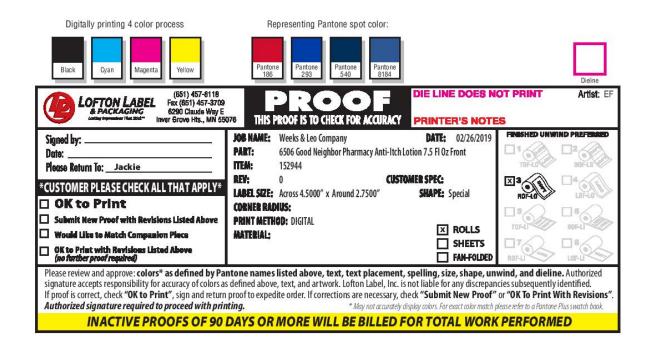
Steroid Free

Relief from itching associated with dry skin, insectr bites, poison ivy and Sunburn

Cools and Soothes







camphor, menthol lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-573	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.5 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
PEG-40 STEARATE (UNII: ECU18C66Q7)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CARBOMER 940 (UNII: 4Q93RCW27E)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
DMDM HYDANTO IN (UNII: BYR0546TOW)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
PEG-100 STEARATE (UNII: YD01N1999R)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
PETROLATUM (UNII: 4T6H12BN9U)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:46 122-573- 10	212 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/25/2020	

Labeler - AMERISOURCEBERGEN DRUG CORPORATION (007914906)

Establishment			
Name	Address	ID/FEI	Business Operations
Weeks & Leo		005290028	manufacture(46122-573)

Revised: 11/2020

AMERISOURCEBERGEN DRUG CORPORATION