LEADER ANTI-ITCH- camphor, menthol 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.

Leader 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

Anti - itch

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

Compare to Sarna Original Anti-Itch lotion

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

LEADER ANTI-ITCH

camphor, menthol lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0546
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0546-1	212 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/21/2020	

Labeler - CARDINAL HEALTH (097537435)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo		005290028	manufacture(70000-0546)

Revised: 1/2020 CARDINAL HEALTH