

**RUGBY ANTI-ITCH- camphor, menthol lotion**  
**RUGBY LABORATORIES**

*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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**Rugby 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

dries the oozing and weeping of poison:

ivy

oak

sumac

**Warning**

For external use only

**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**

**Rugby**®

NDC 0536-1268-12  
Compare to Sama®  
Original Anti-Itch Lotion\*

**Steroid-Free**

**Original Formula**

# Anti-Itch Lotion

**Camphor 0.5%, Menthol 0.5%**

- Relief from itching associated with dry skin, insect bites, poison ivy, and sunburns
- Cools and soothes

**7.5 FL OZ (222 mL)**

## RUGBY ANTI-ITCH

camphor, menthol lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0536-1268

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)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1268-12	212 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/20/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/16/2019	

Labeler - RUGBY LABORATORIES (079246066)

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Weeks & Leo		005290028	manufacture(0536-1268)

Revised: 12/2019

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