FIRE OUT- benzocaine and menthol solution
Randob Ltd.

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.

Drug Facts

Active ingredient

Benzocaine USP 20%

Menthol USP 1%

Purpose

(for pain) Topical Anesthetic

(anti-itch) Antipruritic

Keep Out of Reach of Children

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

Uses

- Temporarily relieves pain and itching of fire ant bites and stings, insect bites and stings, and minor skin irritation.

Warnings

- **For external use only**
- **Do not apply over large areas of the body**
- **Avoid contact with eyes, mouth, and mucous membranes**

Directions

Children under 2 yrs.

- Do not use
- Consult doctor

Adults and children 2 yrs. and older

- Clean area
- Apply to affected area as needed not more than 3 to 4 times a day.

Inactive Ingredients

FD&C Blue #1, Isopropyl Alcohol 15%, PEG-8 Laurate, Water.

Package/Label Principal Display Panel

NEW!

KILLS THE PAIN

STOPS THE ITCH

FIRE OUT™

INSTANT PAIN RELIEF

from:

Fire Ant Stings

also from:

Mosquito Bites Insect Bites
Jellyfish Stings Bee Stings

MAXIMUM STRENGTH

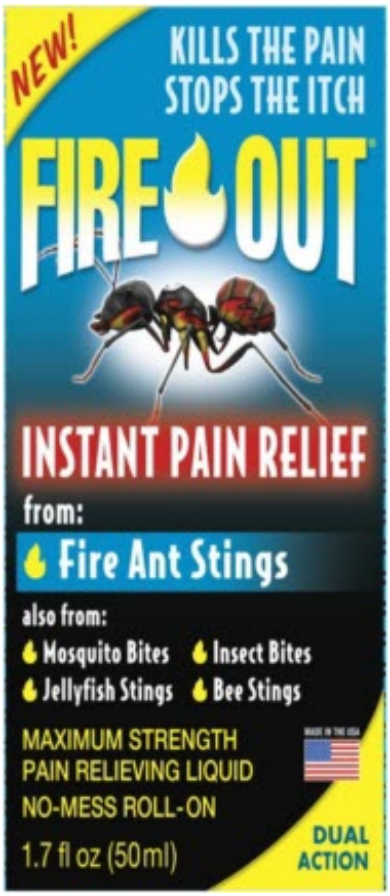
PAIN RELIEVING LIQUID

NO-MESS ROLL-ON

1.7 fl oz (50 ml)

MADE IN THE USA

DUAL ACTION



FIRE OUT

benzocaine and menthol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52412-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	BLUE (Blue)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52412-300-10	1 in 1 CARTON	02/15/2016	
1		50 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:52412-300-20	5 in 1 BLISTER PACK	03/15/2017	03/15/2017
2		0.5 mL in 1 VIAL, SINGLE-USE; 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	part348	02/15/2016	

Labeler - Randob Ltd. (061995007)

Registrant - Randob Ltd. (061995007)

Establishment

Name	Address	ID/FEI	Business Operations
Multi-Pack Solutions		557434805	ANALYSIS(52412-300) , MANUFACTURE(52412-300) , PACK(52412-300) , LABEL(52412-300)

Revised: 4/2019 Randob Ltd.