INSTAFLEX PAIN RELIEF ROLL-ON- menthol liquid
Healthy Directions, 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.

InstaFlex Pain Relieving Roll-On

Drug Facts

Active Ingredient

Menthol (1.25%)

Purpose

Menthol (1.25%).....Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with

- arthritis
- strains
- sprains
- bruises

Warnings

For external use only

Do not use

- with a heating pad, may blister skin
- on open wounds or damaged skin

Ask a doctor before use if you have redness over the affected area

When using this product

- Use only as directed
- avoid contact with eyes
- do not bandage tightly

Stop use and ask a doctor if

- skin redness or excessive skin irritation develops
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again in a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adult and children 12 years of age and older: Apply to affected area no more than 3-4 times daily.

Children under 12 years of age: Consult a doctor.

Other information

Keep product at room termperature and humidity [59-86°F (15-30°C), 40% RH]. Do not freeze. Lot Number and Expiration Date printed below.

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cetyl Alcohol, Citrus Aurantium Dulcis (Orange) Oil, Dimethicone, Ethylhexylglycerin, Eucalyptus Globulus Oil, Clyceryl Stearate SE, Oxygenated Corn Oil, Phenoxyethanol, Polysorbate-20, Sodium Hydroxide, Steareth-20, Water, Xanthan Gum, Zemea (Corn) Propanediol

DOCTOR DEVELOPED

FAST ACTING

PAIN RELIEVING ROLL-ON

Instaflex

PAIN RELIEF

Formualted with an Exclusive Oxygenated Oil

Powerful roll-on relief for arthritis, joint & muscle pain

- Deep Penetrating
- Fast Acting
- Pleasant Smelling
- Non-Greasy
- No Mess

Net wt. 2.5 oz (71 g)

INSTAFLEX PAIN RELIEF ROLL-ON

menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70015-670
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CORN OIL (UNII: 8470G57WFM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARETH-20 (UNII: L0Q8IK9E08)	
WATER (UNII: 059QF0KO0R)	
ORANGE OIL (UNII: AKN3KSD11B)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70015-670-25	1 in 1 CARTON	10/21/2019	
1		71 g in 1 BOTTLE, WITH APPLICATOR; 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	10/21/2019	

Labeler - Healthy Directions, LLC (150261183)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(70015-670)

Revised: 10/2019 Healthy Directions, LLC