INSTAFLEX PAIN RELIEF- menthol, methyl salicylate spray 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 Spray

Drug Facts

Active Ingredients

Menthol (5%)

Methyl Salicylate (10%)

Purpose

Menthol (5%).....Topical Analgesic

Methyl Salicylate (10%).....Topical Analgesic

Uses

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

- simple backache
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only

Flammable

Flammable

- do not use near heat or flame or while smoking
- avoid long term storage above 104F (40C)
- do not puncture or incinerate
- contents under pressure
- do not store at temperature above 120F (49C)

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 and mucous membrane

- avoid inhalation of fumes
- spray away from face
- 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: Shake and apply liberally at least 4 inches away from affected area no more than 3-4 times daily. Let dry or rub in for greater efficacy.

Children under 12 years of age: Consult a doctor.

Other information

Do not freeze. For Lot Number and Expiration Date, see bottom of can.

Inactive ingredients

Citrus Aurantium Dulcis (Orange) Oil, Ethylhexylglycerin, Eucalyptus Globulus Oil, Methylsulfonylmethane (MSM), Oxidized Corn Oil, Phenoxyethanol, SD-Alcohol 40B.

EXTRA STRENGTH

PAIN RELIEVING SPRAY

Instaflex

PAIN RELIEF

Formulated with an Exclusive Oxygenated Oil

Powerful, EXTRA STRENGTH, doctor-developed relief for arthritis, joint & muscle pain

- Deep Penetrating
- Fast Acting
- Quick Drying
- 360 Continuous Spray

EXTRA STRENGTH

PAIN RELIEVING SPRAY

Net wt. 4.0 oz (113 g)



INSTAFLEX PAIN RELIEF

menthol, methyl salicylate spray

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70015-675
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
CORN OIL (UNII: 8470G57WFM)				
PHENO XYETHANOL (UNII: HIE492ZZ3T)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
ORANGE OIL (UNII: AKN3KSD11B)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)				
ALCOHOL (UNII: 3K9958V90M)				

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70015-675- 40	1 in 1 CARTON	12/11/2019		
1		113 g in 1 BOTTLE, SPRAY; 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	12/11/2019	

Labeler - Healthy Directions, LLC (150261183)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source, LLC		080354456	manufacture(70015-675)	

Revised: 12/2019 Healthy Directions, LLC