FLEXSPORT ROLL ON- methyl salicylate liquid Pharmadel 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.

FlexSport Roll On - MS 15%

Drug Facts

Active ingredient and Purpose

Active ingredient	Purpose
Menthol 16%	Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises

Warnings

For external use only. Avoid contact with the eyes.

Flammable: keep away from fire or flame.

When using this product

- do not bandage tightly or use with a heating pad
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- use only as directed
- adults and children over 12 years: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- store at temperatures not exceeding 15°-30°C (59°- 86°F)
- avoid excessive heat and humidity

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, alcohol, capsaicin, glycerin, isopropyl myristate, propylene glycol, trolamine, water

Questions or Comments?

1-866-359-3478 (M-F) 9 AM – 5 PM EST or www.pharmadel.com

Principal Display Panel

Topical Analgesic Liquid

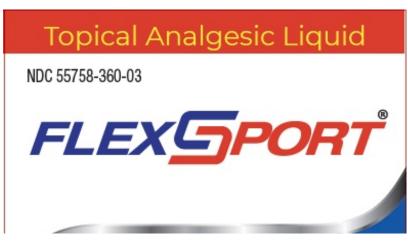
FlexSport

Pain Relief

ROLL-ON

- Muscle & Joint Pain
- Backaches
- Arthritis

3 fl oz (89 mL)





FLEXSPORT ROLL ON

methyl salicylate liquid

Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55758-360

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLATE 15 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)			
DMDM HYDANTOIN (UNII: BYR0546TOW)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
TROLAMINE (UNII: 903K93S3TK)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
CAPSAICIN (UNII: S07044R1ZM)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
MENTHOL (UNII: L7T10EIP3A)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			

F	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:55758- 360-03	1 in 1 BOX	04/04/2021				
1		89 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part348	04/04/2021			

Labeler - Pharmadel LLC (030129680)

Revised: 4/2021 Pharmadel LLC