FLEXITOL FOOT AND KNEE PAIN RELIEF- methyl salicylate gel LaCorium Health USA Inc.

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.

Flexitol® Foot & Knee Pain Relief Gel

Drug Facts

Active ingredient

Methyl Salicylate 10%

Purpose

Topical analgesic

Uses

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

- strains
- bruises
- sprains
- arthritis

Warnings

For external use only

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water
- do not use on broken skin
- do not bandage tightly
- do not use other than as directed

Do not use on broken skin

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

Directions

Adults and children 2 years of age and older:

apply to affected area not more than 3 - 4 times daily

Children under 2 years of age:

• consult a physician

Other Information

- Store between 50-86°F in a dry place
- Do not use if tube seal is broken or appears tampered with

Inactive ingredients

arnica montana flower extract, benzyl alcohol, C13-14 isoparaffin, ethanol, laureth-7, PEG-40 hydrogenated

Questions or Comments?

Call Toll Free 1-866-478-3338 usainfo@flexitol.com www.flexitol.com

DISTRIBUTED BY: LaCorium Health USA Inc801 Broad St, Suite 600
Chattanooga, TN 37402

PRINCIPAL DISPLAY PANEL - 56 g Tube Carton

NDC: 43251-2400-1

Flexitol®

FOOT & KNEE PAIN RELIEF GEL

PAIN RELIEF

FOR FOOT & KNEE PAIN ASSOCIATED WITH:

- STRAINS
- BRUISES
- SPRAINS
- ARTHRITIS

NON-GREASY, QUICK ABSORBING

WITH METHYL SALICYLATE 10%

TOPICAL ANALGESIC

AUSTRALIAN MADE & OWNED

Net Wt. 2 oz (56 g) GEL

FLEXITOL FOOT AND KNEE PAIN RELIEF

methyl salicylate gel

	Product Information
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:43251-2400

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl Salicylate	100 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
Alcohol (UNII: 3K9958V90M)		
C13-14 Isoparaffin (UNII: E4F12ROE70)		
Laureth-7 (UNII: Z95S6G8201)		
Arnica Montana Flower (UNII: OZ0E5Y15PZ)		
Peppermint oil (UNII: AV092KU4JH)		
Benzyl alcohol (UNII: LKG8494WBH)		
Tocopherol (UNII: R0ZB2556P8)		
POLYACRYLAMIDE (1300000 MW) (UNII: SC5Y4X78TG)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43251-2400-1	1 in 1 CARTON	01/01/2022	
1		56 g in 1 TUBE; 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	01/01/2022	

Labeler - LaCorium Health USA Inc. (111254392)

Establishment			
Name	Address	ID/FEI	Business Operations
Ross Laboratories Aust Pty Ltd		753529114	MANUFACTURE(43251-2400) , LABEL(43251-2400) , ANALYSIS(43251-2400) , PACK(43251-2400)

Revised: 6/2022 LaCorium Health USA Inc.