DOLORAN- menthol, camphor, methyl salicylate ointment Hector Rivera Garzon y Compania. S. en C.

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.

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Active Ingredients

Active Ingredients Purpose

Menthol	2.0% Topical Analgesic
Camphor	8.0% Topical Analgesic
Methyl Salicylate	8.0% Topical Analgesic

Purpose

Topical Analgesic

Use

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

- **Do not use** on wounds or damaged skin with a healing pad
- **Do not use** on a child under 12 years of age with arthritis-like conditions

Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of htis product and consult a doctor. Do not apply to wounds or damaged skin. Do not bandage tightly

Keep out of reach of children to avoid accidental ingestion.

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

Directions

- Use only as directed
- Adults and children 12 years of age and older; apply to affected area not ore than 3 to 4 times daily
- Children under 12 years of age; ask a doctor

Inactive Ingredients (Petrolatum, anhydrous lanolin, parrafin)



DOLORAN

menthol, camphor, methyl salicylate ointment

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71016-001			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.08 g in 1 g				
CAMPHOR, (-)- (UNII: 213N3S8275) (CAMPHOR, (-) UNII:213N3S8275)	CAMPHOR, (-)-	0.08 g in 1 g				
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.02 g in 1 g				

Inactive Ingredients				
Ingredient Name	Strength			
LANOLIN (UNII: 7EV65EAW6H)				

PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics					
Color		Score			
Shape	ROUND	Size			
Flavor		Imprint Code			
Contains					

F	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:71016-001-20	1 in 1 BOX	10/24/2016				
1		20 g in 1 BOX; 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	10/24/2016				

Labeler - Hector Rivera Garzon y Compania. S. en C. (881238799)

Revised: 12/2019 Hector Rivera Garzon y Compania. S. en C.