ROCAINOL TOPICAL ANALGESIC- methyl salicylate, menthol ointment Compania Internacional de Comercio, S.A.P.I de C.V.

Rocainol TOPICAL ANALGESIC OINTMENT

Drug Facts

Active ingredients

Methyl salicylate 16% Menthol 8%

Purpose

External analgesic

Uses

Temporary relief of minor aches and pains associated with • arthritis • simple backache • bruises • sprains

Warnings

For External use only

Do not use

on pregnant women and children under 12 years of age unless directed by a doctor

Do not apply

to wounds or damaged skin Do not bandage tightly

Discontinue use

if excessive irritation of the skin develops

Keep this and all drugs out of the reach of children.

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 this product and consult a doctor

Directions

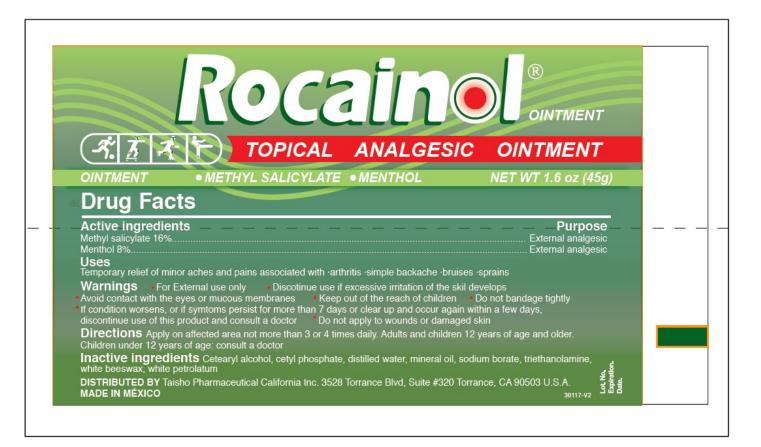
Apply on affected area not more than 3 or 4 times daily. Adults and children 12 years of age and older. Children under 12 years of age: consult a doctor

Inactive ingredients

Cetearyl alcohol, cetyl phosphate, distilled water, mineral oil, sodium borate, triethanolamine, white beeswax, white petrolatum

Package Labeling:





ROCAINOL TOPICAL ANALGESIC

methyl salicylate, menthol ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54312-825
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	16 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 g in 100 g	

Inactive Ingredients		
Strength		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54312-825- 01	1 in 1 PACKAGE	05/30/2019	
1		45 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 Drug	M017	09/30/2013	

Labeler - Compania Internacional de Comercio, S.A.P.I de C.V. (822165213)

Establishment				
Name	Address	ID/FEI	Business Operations	
Compania Internacional de Comercio, S.A.P.I. de C.V.		822165213	manufacture(54312-825)	

Revised: 10/2023 Compania Internacional de Comercio, S.A.P.I de C.V.