

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

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

Rocainol® OINTMENT

TOPICAL ANALGESIC OINTMENT

• OINTMENT
• METHYL SALICYLATE
• MENTHOL

NET WT 1.6 oz (45g)

Lot. No.:
Expiration Date:

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Methyl salicylate 16%.....
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Rocainol® OINTMENT

TOPICAL ANALGESIC OINTMENT

Rocainol® OINTMENT

OINTMENT • METHYL SALICYLATE • MENTHOL NET WT 1.6 oz (45g)

Drug Facts (continued)

Do not apply to wounds or damaged skin	Discontinue use if excessive irritation of the skin develops
Do not bandage tightly	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 Cetylalcohol, cetyl phosphate, distilled water, mineral oil, sodium borate, triethanolamine, white beeswax, white petrolatum

DISTRIBUTED BY TaiSho Pharmaceutical California Inc.
3528 Torrance Blvd, Suite #320
Torrance, CA 90503 U.S.A.
MADE IN MEXICO



ROCAINOL[®] OINTMENT



TOPICAL ANALGESIC OINTMENT

OINTMENT • METHYL SALICYLATE • MENTHOL

NET WT 1.6 oz (45g)

Drug Facts

Active ingredients	Purpose
Methyl salicylate 16%.....	External analgesic
Menthol 8%.....	External analgesic

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

Warnings •For External use only •Discontinue use if excessive irritation of the skin develops
•Avoid contact with the eyes or mucous membranes •Keep out of the reach of children •Do not bandage tightly
•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 •Do not apply to wounds or damaged skin

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

DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A.
MADE IN MEXICO

30117-V2 Lot, No., Expiration Date.

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

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
TROLAMINE (UNII: 9O3K93S3TK)	
WHITE WAX (UNII: 7G1J5DA97F)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	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.