

PAIN RELIEVING BALM- menthol, methyl salicylate liquid

TopCo

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.

Drug Facts

Active ingredients

Menthol 7.6%.....Topical Analgesic
Methyl Salicylate 29%.....Topical Analgesic

Purpose

Uses

temporarily relieves minor pain associated with:

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

Warnings

For external use only

Allergy Alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product • use only as directed • avoid contact with eyes or mucous membranes • do not bandage tightly or use with a heating pad • do not apply to wounds or damaged skin

Stop use and ask 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 healthcare professional before use

Keep out of reach of children.

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

Directions

Adults and children over 12 years: • apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary, but not more than 4 times daily.

Children under 12 years: ask a doctor

Inactive ingredients

Paraffin, White Petrolatum

<p>Drug Facts</p> <p>Active ingredients Menthol 7.6%.....Topical Analgesic Methyl Salicylate 29%.....Topical Analgesic</p> <p>Purpose</p> <p>Uses temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • bruises • muscle sprains • cramps</p> <p>Warnings For external use only</p> <p>Allergy Alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.</p> <p>When using this product • use only as directed • avoid contact with eyes or mucous membranes • do not bandage tightly or use with a heating pad • do not apply to wounds or damaged skin</p> <p>Stop use and ask 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</p> <p>if pregnant or breast-feeding, ask a healthcare professional before use</p>	<p>EXTRA STRENGTH</p> <h1>Pain Relieving Balm</h1> <p>Therapy Pain Relief Balm</p> <p>Compare to Icy Hot® active ingredients*</p> <p>NET WT 3.5 OZ (99.2 g)</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions Adults and children over 12 years: • apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary, but not more than 4 times daily. Children under 12 years: ask a doctor</p> <p>Inactive ingredients Paraffin, White Petrolatum.</p> <p><small>*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Icy Hot®. DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT ROAD, SKOKIE, IL 60077 ©TOPCO POU909 QUESTIONS? 1-888-423-0139 topcare@topco.com</small></p> <p><small>This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed!</small></p> 
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PAIN RELIEVING BALM

menthol, methyl salicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-738
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	7.6 g in 100 g
Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl Salicylate	29 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Paraffin (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-738-04	99.2 g in 1 PACKAGE; Type 0: Not a Combination Product	11/16/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/16/2011	

Labeler - TopCo (006935977)

Registrant - Product Quest mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest mfg		927768 135	manufacture(36800-738) , label(36800-738)

Revised: 7/2018

TopCo