

MENTHOL AND METHYL SALICYLATE - menthol and methyl salicylate stick
H.J. Harkins Company, 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.

Menthol and Methyl Salicylate

PAIN RELIEVING STICK

Drug Facts

Active ingredient

Menthol 10%

Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

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

Warnings

For external use only

SEE INSIDE LABEL FOR COMPLETE DRUG FACTS

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

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a 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 health care 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 12 years or younger: ask a doctor

Inactive ingredients

ceresin, cyclomethicone, hydrogenated castor oil, microcrystalline wax, paraffin, PEG-150 distearate, propylene glycol, stearic acid, stearyl alcohol (245-111)

Repacked by:
H.J. Harkins Company, Inc.
513 Sandydale
Nipomo, CA 93444

52959-028-03 #XXX CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT O REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

MENTHOL AND METHYL SALICYLATE

Lot #: ICH101NC
Mfg: CHATTEM IN
Exp: 10/11 Compare to: Ex. Strength
Mfg Chattanooga, Mfg. NDC: 41167-089-80
Loc.: TN Pill ID: ---

Take as directed by your Doctor or
See outsert for usual dosage information

MENTHOL AND METHYL SALICYLATE
52959-028-03 Qty 1.75oz
10/11 Lot ICH101NC
Ex. Strength 41167-089-80

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Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

MENTHOL AND METHYL SALICYLATE			
menthol and methyl salicylate stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-028(NDC:41167-0089)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-028-03	49 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/01/1991	

Labeler - H.J. Harkins Company, Inc. (147681894)**Establishment**

Name	Address	ID/FEI	Business Operations
Chattem Plant 1		003336013	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Chattem Plant 2		830410721	MANUFACTURE