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:

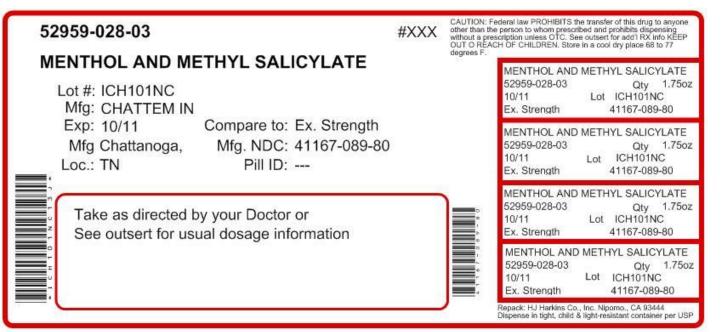
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

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



MENTHOL AND METHYL SALICYLATE

menthol and methyl salicylate stick

Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-028(NDC:41167-0089)	
Route of Administration	TOPICAL			

	rength Stre	ength				
MEN	-	n 100 g				
MET	CYLATE 30 g i	in 100				
Ina	ctive Ingredients					
		Ingredient Name	<u>!</u>		Strength	
CER	ESIN (UNII: Q1LS2UJO3A	A)				
СҮС	LOMETHICONE (UNII: I	VMQ347994Z)				
HYD	ROGENATED CASTOR	OIL (UNII: ZF94AP8MEY)				
MIC	ROCRYSTALLINE WAX	K (UNII: XOF597Q3KY)				
PAR	AFFIN (UNII: 1900E3H2Z	E)				
PEG	-150 DISTEARATE (UNI	l: 6F36Q0I0AC)				
PRO	PYLENE GLYCOL (UNI	I: 6DC9Q167V3)				
STE	ARIC ACID (UNII: 4ELV7	Z65AP)				
STE	ARYL ALCOHOL (UNII:	2KR89I4H1Y)				
Pac	kaging					
#	Item Code	Package Description	Marketing Start I	Date Ma	rketing End Date	
1 N	DC:52959-028-03	49 g in 1 JAR				
Ma	rketing Inform	ation				
	Marketing Category	Application Number or Mon	ograph Citation Mark	eting Start Date	Marketing En	d Dat
	MONOGRAPH NOT FINA		06/01			

La	bel	ler	-	H.J.	Harkins	Company,	Inc.	(147681894)
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Establishment

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

Establishment

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

Revised: 3/2012

H.J. Harkins Company, Inc.