

CVS EXTRA STRENGTH PAIN RELIEF - menthol, methyl salicylate gel

CVS Pharmacy

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 ingredient

Purpose

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

Uses temporary relieves minor pain associated with:

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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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 the eyes or mucous membranes
- do not bandage tightly or use with a heating pad - do not apply to wounds or damaged skin

Ask a doctor before use 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 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 12 years of age and older:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children under 12 years of age: consult a doctor

Inactive Ingredients paraffin, petrolatum

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Compare to the active ingredients in Icy Hot®*

Extra Strength PAIN RELIEF

**COLD TO DULL THE PAIN
HEAT TO RELAX IT AWAY**

Pain Relieving Balm



NET WT 3.5 OZ (99.2 g)

Drug Facts (continued)

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*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Icy Hot®

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One CVS Drive, Woonsocket, RI 02895
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CVS EXTRA STRENGTH PAIN RELIEF

menthol, methyl salicylate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-620
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	76 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	290 mg in 1 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:59779-620-35	99.2 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2010

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