# CVS HEALTH COLD AND HOT PAIN RELIEVING EXTRA STRENGTH- menthol, methyl salicylate cream 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.

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#### **Drug Facts**

#### **Active ingredient**

Menthol 10%

Methyl salicylate 30%

#### **Purpose**

Menthol - Topical analgesic

Methyl salicylate - Topical analgesic

#### Uses

temporarily relieves minor aches and pains of muscles and joints associated with:

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

#### **Warnings**

## For external use only

## When using this product

- use only as directed
- do not get into eyes or on mucous membranes
- do not apply to wounds or irritated or damaged skin
- do not bandage tightly
- do not use with a heating pad or apply external heat

## Stop use and ask a doctor if

- skin redness or excessive irritation of the skin occurs
- condition worsens
- 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 and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor

#### **Inactive Ingredients**

glyceryl stearate, isoceteth-20, poloxamer, purified water, sodium lauryl sulfate, sorbitan monostearate, trolamine

### **Principal Display Panel**



#### CVS HEALTH COLD AND HOT PAIN RELIEVING EXTRA STRENGTH

menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-791
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Ingredient Name Basis of Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	100 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	300 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
ISOCETETH-20 (UNII: O020065R7Z)		

POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TROLAMINE (UNII: 903K93S3TK)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59779-791- 01	1 in 1 CARTON	10/03/2016		
1		85 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part348	10/03/2016			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

## Labeler - CVS Pharmacy (062312574)

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