

CASTIVA COOLING- menthol and methyl salicylate cream
Humco Holding Group, 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.

Castiva Cooling

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Drug Facts

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Active Ingredient

Methyl Salicylate 14%

Purpose

Topical Analgesic

Use

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains.

Warnings

For external use only.

Allergy alert. If prone to allergic reaction from aspirin or salicylate, consult a doctor before use.

Do not use

otherwise than as directed, on damaged skin, on open wounds, with a heating pad.

Stop and ask a doctor if

condition worsens, symptoms persist for more than 7 days, or clear up and occur again within a few days.

When using this product

avoid contact with eyes. Do not bandage tightly.

If pregnant or breast feeding,

ask a health professional before use.

Drug Facts	
Active ingredients	Purpose
Menthol 5%.....	Topical Analgesic
Methyl Salicylate 14%.....	Topical Analgesic
Uses For the temporary relief of minor aches and pains of muscles and joints associated with ■ Simple backache ■ Arthritis ■ Strains ■ Bruises ■ Sprains.	
Warnings ■ For External Use Only	
Allergy Alert If prone to allergic reaction from aspirin or salicylate, consult a doctor before use.	
Do not use ■ Otherwise than as directed ■ On damaged skin ■ On open wounds ■ With a heating pad.	
Stop use and ask a doctor if ■ Condition worsens ■ Symptoms persist for more than 7 days or clears up and occurs again within a few days.	
When using this product ■ Avoid contact with eyes. ■ Do not bandage tightly.	
If pregnant or breast feeding , ask a health professional before use.	
Keep out of reach of children to prevent accidental poisoning. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	
Directions	
■ Adults and children 12 yrs. of age and older: Apply to affected area no more than 3 to 4 times daily.	
■ Children under 12 yrs. of age: Consult a doctor.	
Other information Store at room temperature.	
Inactive ingredients Castor oil, diazolidinyl urea, glyceryl monostearate, isopropyl palmitate, lecithin, methylparaben, PEG-100 stearate, poloxamer 407, polyglyceryl-3 distearate, potato starch modified, propylene glycol, propylparaben, purified water and SD alcohol 40-B.	

Distributed by: HUMCO Texarkana, TX 75501

Cooling
Castiva™

Methyl Salicylate 14%
Menthol 5%

**Arthritis Pain
Relief Lotion**

With Natural
Castor Oil Base

**Deep Penetrating
Fast Acting**

4 OZ (113 G)



CASTIVA COOLING

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-0129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	140 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
STARCH, POTATO (UNII: 8I089SAH3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-0129-94	1 in 1 CARTON	12/01/2006	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/01/2006	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(0395-0129) , label(0395-0129) , analysis(0395-0129)

