

CALYPXO HP PAIN RELIEF- methyl salicylate, menthol cream
Asclemed USA, Inc

Drugs Facts

Active Ingredients

Methyl Salicylate.....15.00%

Menthol.....10.00%

Purpose

Topical Analgesic

Topical Analgesic

Uses

For temporary relief of minor aches and pains associated with simple backaches, arthritis, bruises, sprains and cramps.

Warning

- For external use only.
- Avoid contact with eyes and mucous membranes.

Do not

- bandage tightly or cover treated areas.
- use with heating pad.
- apply to open wounds or damages skin.
- A mild burning sensation may occur.
- If severe burning sensation occurs, discontinue use immediately.
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

- If swallowed, consult physician.
- If pregnant or breast feeding, contact physician prior to use.

Directions

For adults apply directly to affected area. Repeat as necessary, but do not use more than 3-4 times daily.

Additional Information

Store at room temperature.

Other Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Ethylhexylglycerin, Isopropyl Myristate, PEG-8, Phenoxyethanol, Sodium Lauryl Sulfate, Triethanolamine.

Principal Display Panel

NDC 76420-999-01

Calypxo HP

Pain Relief Cream

4 oz (113g)

Distributed by:

Enovachem

PHARMACEUTICALS

Torrance, CA 90501

(310) 320-0100

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methyl salicylate, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-999
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-999-01	113 g in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/10/2020	

Labeler - Asclemed USA, Inc (059888437)