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

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

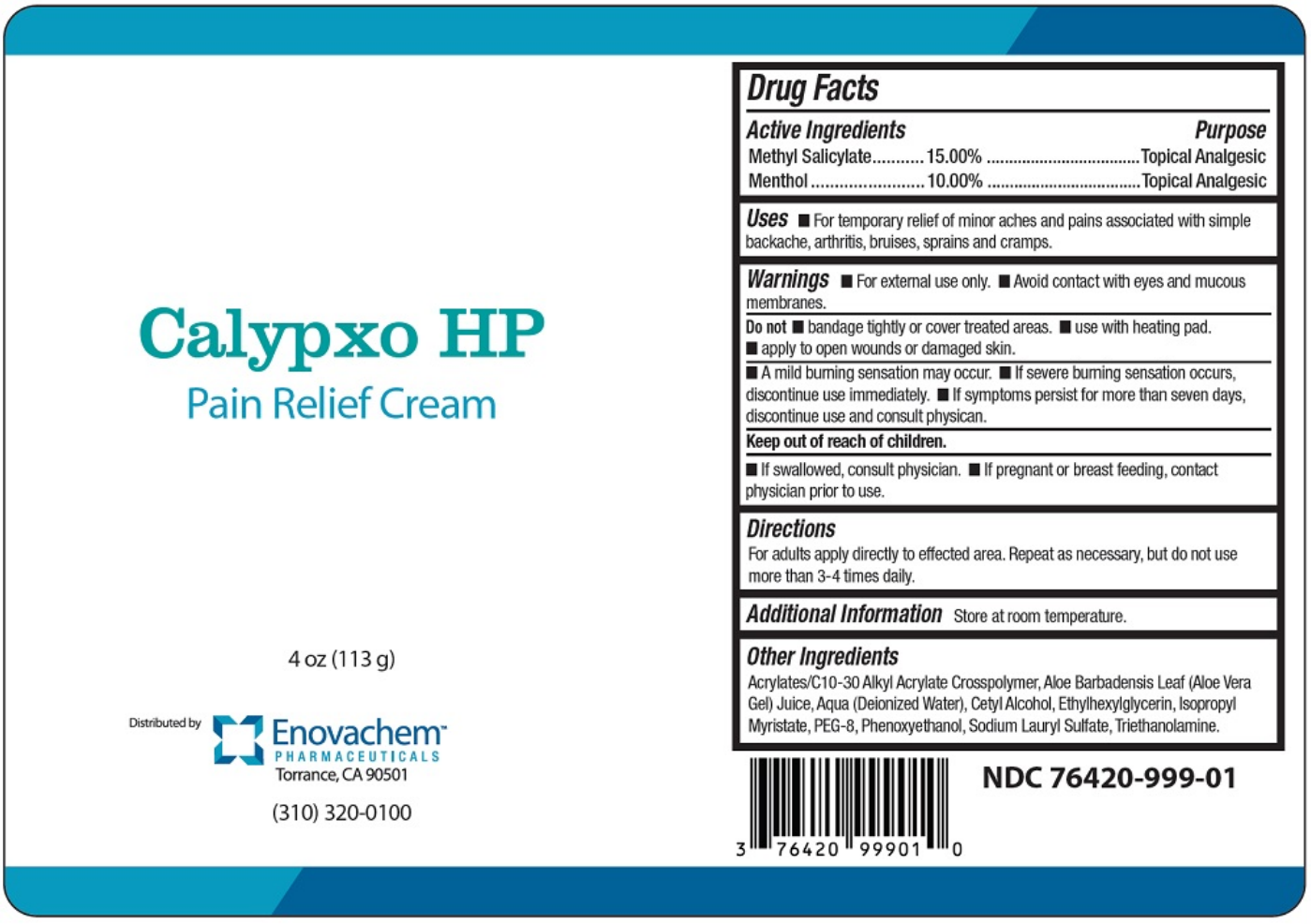
NDC 76420-999-01

Calypxo HP

Pain Relief Cream

4 oz (113g)

Distributed by:
Enovachem
PHARMACEUTICALS
Torrance, CA 90501
(310) 320-0100



CALYPXO HP PAIN RELIEF

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 not final	part348	12/10/2020	

Labeler - Asclemed USA, Inc (059888437)

Revised: 12/2020 Asclemed USA, Inc