CALYPXO PAIN RELIEF- methyl salicylate, menthol cream
Advanced Rx of Tennessee, LLC

Calypxo Cream

Drugs Facts

Active Ingredients

Methyl Salicylate……10.00%

Menthol……3.00%

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.

Do not use with heating pad.

Do not 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.

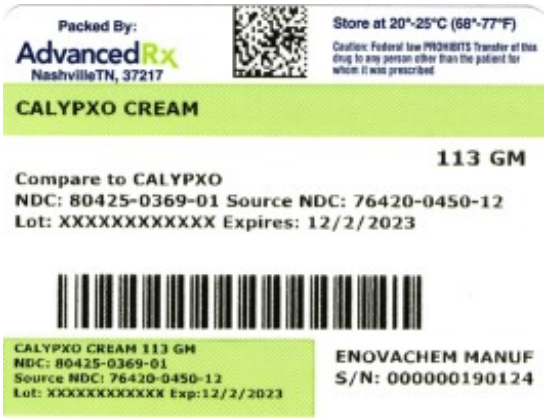
Additional Information

Store at room temperature.

Other Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Diazolidinyl Urea, Isopropyl Myristate, Methyl Paraben, PEG-8, Propyl Paraben, Propylene Glycol, Sodium lauryl Sulfate, Triethanolamine.

Principal Display Panel



CALYPXO PAIN RELIEF

methyl salicylate, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0369(NDC:76420-450)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 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)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0369-1	113 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2023	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0369)

Revised: 12/2024 Advanced Rx of Tennessee, LLC