ALO THERAPEUTIC MASSAGE- menthol, histamine dihydrochloride cream Theraplex Solutions

Alo Therapeutic Massage

Drug Facts

Active Ingredients

Menthol 3.00% Histamine Dihydrochloride 0.100%

Purpose

External Analgesic

Uses

For temporary relief of minor aches and pains associated with backache, arthritis, bruises and sprains.

Warnings

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds or damages skin.
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

If swallowed, consult physician. Do not bandage tightly.

If pregnant or breast feeding,

contact physician prior to use.

Directions

- Apply directly to effected area.
- Do not use more than four times per day.

Other Ingredients

Aqua (Deionized Water), Butylene Glycol, Carbomer, Cetyl Alcohol, Ethylhexylglycerin, Dimethyl Sulfone(MSM), Glyceryl Stearate, Healianthus Annuus (Sunflower) Oil, Mentha Viridis (Spearmint) Oil, Mineral Oil, Parfum (Fragrance), PEG-100 Stearate,

Distributed by:

THERAPLEX SOLUTIONS

Miami, Florida 33298

Questions? call 305.609.4229

www.alo-21.com

Alo THERAPEUTIC MASSAGE CREAM; PAIN RELIEVING; DEEP PENETRATING, PAIN RELIEF FROM ARTHRITIS; SORE MUSCLES AND JOINTS; BACK PAIN; BRUISES AND SPRAINS STIMULATES CIRCULATION TO SPEED HEALING 4 fl oz Drug Facts

Alo Therapeutic Massage Cream 4oz/118g (51457-000-04)

Phenoxyethanol, SD-Alcohol 40B, Triethanolamine, Xanthan Gum.



T H E R A P E U T I C MASSAGE CREAM

PAIN RELIEVING

DEEP PENETRATING, PAIN RELIEF FROM:

- ARTHRITIS .
- SORE MUSCLES & JOINTS .
 - BACK PAIN
 - **BRUISES & SPRAINS**

STIMULATES CIRCULATION TO SPEED HEALING

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ALO THERAPEUTIC MASSAGE

menthol, histamine dihydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51457-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g	
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SPEARMINT OIL (UNII: C3M81465G5)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 903K93S3TK)	

F	Packaging			
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:51457-000- 04	118 g in 1 TUBE; Type 0: Not a Combination Product	02/03/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/07/2012	

Labeler - Theraplex Solutions (078500057)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source, LLC		080354456	manufacture(51457-000)	

Revised: 11/2023 Theraplex Solutions