MERCY PAIN RELIEVING- menthol lotion
Cloud 9 Naturally

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.

MERCY PAIN RELIEVING LOTION

Drug Facts

Active ingredient

Menthol 1.3%

Purpose

Topical Analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints associated with

• simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only

When using this product

• avoid contact with the eyes and mucous membranes

• do not apply to wounds or damaged skin

• do not bandage tightly

Stop use and ask a doctor if

• condition worsens

• symptoms persist for more than 7 days

• clear up and occur again within a few days

If pregnant or breast-feeding, consult a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

• children under 2 years of age: consult a doctor.

Inactive ingredients

Cetyl Alcohol, Fragrance, Glycerin, Methylsulfonylmethane (MSM), Olive (Oleo Europaea) Oil,

Stearic Acid, Water

Other information

do not use if seal or cap is broken.

Questions?

1-403-348-9704, Mon-Fri, 9AM to 5 PM.

You may also report serious side effects to this phone number.

Soothes minor pain of

• muscles • joints • backache • arthritis

Manufactured by:

Cloud 9 Naturally Inc,

53840 National Rd, Lower unit,

Bridgeport, Ohio, 43912 USA

www.cloud9naturally.com

Packaging

MERCY PAIN RELIEVING

menthol lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72070-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72070-100-01	113.4 g in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/18/2018	

Labeler - Cloud 9 Naturally (255353633)

Establishment

Name	Address	ID/FEI	Business Operations
Cloud 9 Naturally		255353633	manufacture(72070-100)

Revised: 5/2018 Cloud 9 Naturally