

LORNAMEAD LYPSYL- petrolatum and menthol paste

Lornamead

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.

Drug Facts

Active ingredients

Petrolatum 62% Skin Protectant

Menthol 0.6%External Analgesic

Uses

- For the temporary relief of pain & itching associated with cold sores and fever blisters
- Temporarily protects and helps relieve chapped or cracked lips

For External Use Only. When using this product do not use in or near the eyes. If contact occurs, rinse eyes thoroughly with water and obtain medical attention. **Stop use and ask a doctor** if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Directions

Adults and children 12 years of age and older: Apply directly to cold sore or fever blister 1 to 3 times daily

Children under 2 years of age: Consult a doctor

Apply directly to cold sore or fever blister 1 to 3 times daily **Children under 2 years of age:** ask a doctor

Other Information

Store between 15 - 30C (59-86F)

Inactive ingredients

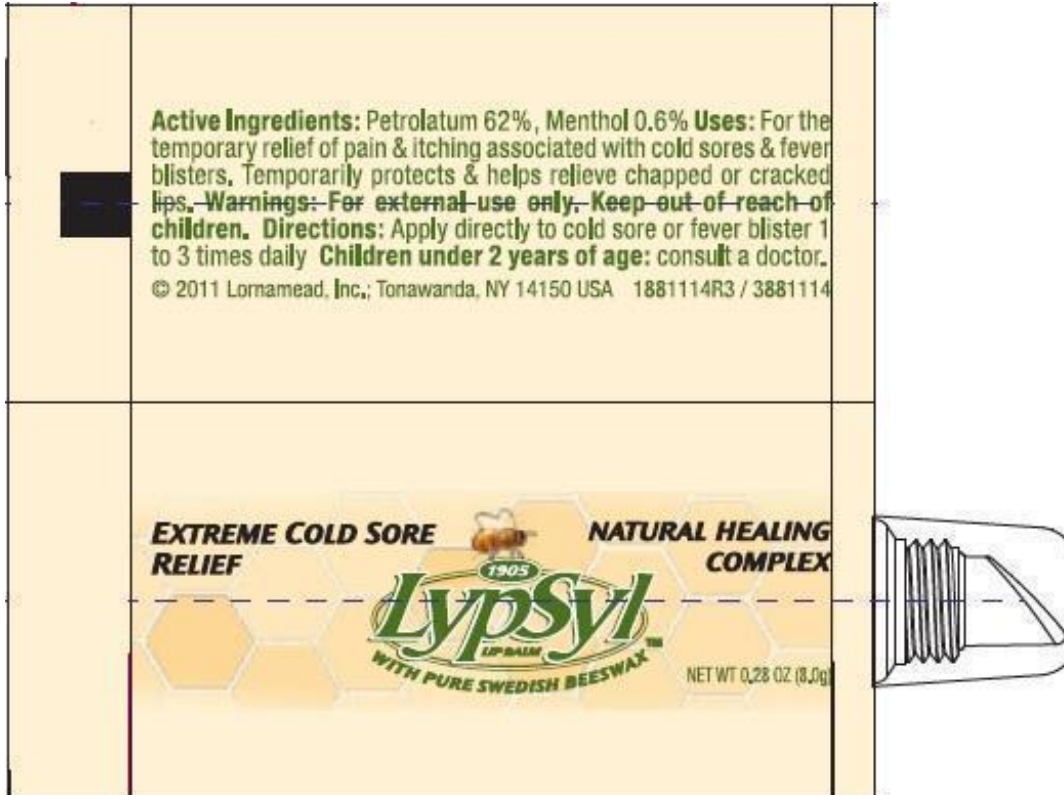
Beeswax, Polyisobutene, Hydrogenated Polyisobutene, Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer, Pentaerythrityl Tetracaprylate/Tetracaprate, Eucalyptus Globulus Leaf Extract, Melaleuca Alternifolia (Tea Tree) Extract, Ceretified Organic Butyrospermum Parkii (Shea Butter) Fruit, Aloe Barbadosensis Leaf Extract, Lysine, Dimethicone, Allantoin, Tocopheryl Acetate (Vitamin E Acetate), Bisabolol, Chamomilla Recutita (Matricaria) Extract, Lavandula Angustifolia (Lavender) Extract, Mentha Piperita (Peppermint) Oil, Camphor, Zinc Lactate, Ascorbyl Palmitate, Propolis Extract, Helianthus Annuus (Sunflower) Seed Extract, Propylparaben, Titanium Dioxide

mm1.jpg





mm2.jpg



petrolatum paste

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:62721-8114
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (PETROLATUM)	PETROLATUM	65.004 g in 100 g
MENTHOL (MENTHOL)	MENTHOL	0.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN	
ALLANTOIN	
SHEA BUTTER	
YELLOW WAX	
DIMETHICONE	
PENTAERYTHRITYL TETRACAPRYLATE/TETRACAPRATE	
POLYISOBUTYLENE (2300 MW)	
ALOE VERA LEAF	
LEVOMENOL	
.ALPHA.-TOCOPHEROL ACETATE	
JOJOBA OIL	
LAVANDULA ANGUSTIFOLIA FLOWER	
CHAMOMILE	
TITANIUM DIOXIDE	
LYSINE	
HELIANTHUS ANNUUS FLOWERING TOP	
ZINC LACTATE	
ASCORBYL PALMITATE	
EUCALYPTUS GLOBULUS LEAF	
CAMPHOR (NATURAL)	
MELALEUCA ALTERNIFOLIA LEAF	
MENTHA PIPERITA	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:62721-8114-9	1 in 1 CARTON		
1	NDC:62721-8114-2	8 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	02/01/2012	

Labeler - Lornamead (126440440)

Registrant - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(62721-8114), pack(62721-8114)

Revised: 3/2013

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