

**LUMINA NATURES CREATION UNVEILED- menthol cream**  
**Cosmetic Specialty Labs, 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.*

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**Active Ingredient**

Menthol, 4%

**Purpose**

Topical analgesic

**Uses**

temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains • bruises • cramps

**Warnings**

For external use only

**When using this product**•use only as directed •avoid contact with eyes or mucous membranes •do not apply to wounds or damaged skin •do not bandage tightly

**Stop use and ask a physician if**•condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days •redness is present •irritation develops

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

Keep out of reach of children . If case of accidental ingestion, get medical help or contact a poison Control Center right away.

**Directions:**

**Adults and children 2 years of age and older:**•apply generously to affected area •massage into painful area until thoroughly absorbed into skin •repeat as necessary, but no more than 4 time daily

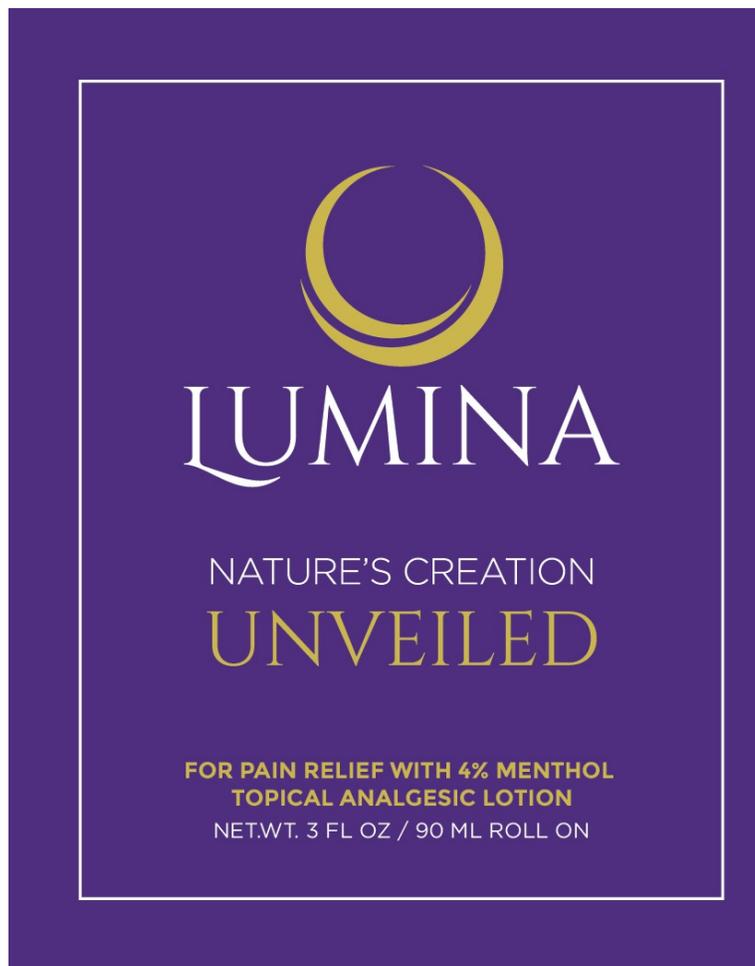
**Children under 2 years of age:** ask a doctor

**Inactive ingredients**

Alcohol, Aloe Barbadosis Leaf Juice, Arnica montana Flower Extract, Butylene Glycol, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Cyanocobalamin, Mentha

piperita (Peppermint) Leaf Oil, Methylsulfonylmethane, Phenoxyethanol, Polysorbate-60, Purified Water, Salix alba (Willow) Bark Extract, Sodium Hyaluronate, Sorbitol, Triethanolamine

## Package Label



<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENT</b> Menthol 4%	<b>PURPOSE</b> Topical Analgesic
<b>USES:</b> Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps	
<b>WARNINGS:</b> For external use only.	
When using this product ■ use only as directed ■ avoid contact with eyes and mucus membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly	
Stop use and ask a physician if ■ condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ irritation develops	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison Control Center right away.	
<b>DIRECTIONS:</b> Adults and children 2 years of age and older: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily Children under 2 years of age: ask a doctor	
<b>INACTIVE INGREDIENTS:</b> Alcohol, Aloe Barbadensis Leaf Juice, Arnica montana Flower Extract, Butylene Glycol, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Cyanocobalamin, Mentha piperita (Peppermint) Leaf Oil, Methylsulfonylmethane, Phenoxyethanol, Polysorbate-60, Purified Water, Salix alba (Willow) Bark Extract, Sodium Hyaluronate, Sorbitol, Triethanolamine.	



NDC 58133-591-03

Distributed by:  
Oasis Health LLC  
2801 Ocean Drive, Suite 300  
Vero Beach, FL 32963  
877-627-4707 | www.oasis.care

## LUMINA NATURES CREATION UNVEILED

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58133-591
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>SALIX ALBA BARK</b> (UNII: 205MXS71H7)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-591-03	90 mL in 1 CYLINDER; Type 0: Not a Combination Product	05/03/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/03/2023	

**Labeler** - Cosmetic Specialty Labs, Inc. (032973000)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-591) , pack(58133-591) , label(58133-591)