

**HOMEOPATHIC LIP BALM- arnica montana ointment**  
**Cosmetic Specialty Labs, Inc.**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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**Real Time Pain Relief Homeopathic Lip Balm**

**Active Ingredient**

Arnica Montana (2X H.P.U.S.)

\*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

**Purpose**

Pain

**Uses**

Temporarily relieves symptoms of pain and inflammation.

**Warnings**

For external use only.

- If swallowed, get medical help or contact a Poison Control Center Immediately.
- Test for allergy by rubbing small amount on skin first.
- Do not use if allergic to or hypersensitive to any ingredient.
- If condition worsens or does not improve consult a doctor.

**When using this product**

- Avoid contact with eyes

**Stop use and ask a doctor if:**

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present
- Irritation develops

Keep all medicines out of reach of children.

**Directions**

Apply to affected area 2 times daily or as needed.

**Inactive Ingredients**

Petrolatum, Synthetic Beeswax, Isopropyl Palmitate, Menthol, Lanolin, Tocopheryl Acetate, Cocos Nucifera (Coconut) Oil, Natural Flavor, Lavandula Angustifolia (Lavender) Oil, Glycerin, Chamomilla Recutita (Matricaria) Flower Extract, Butyrospermum Parkii (Shea) Butter, Mentha Piperita (Peppermint)

Leaf Oil, Isopropyl Myristate, Also Barbados Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Camphor, Butylene Glycol, Stevia Rebaudiana Leaf/Stem Extract.

**Principal Display Panel, Drug Facts**

	<p><b>Homeopathic Lip Balm</b></p> <p>Net Wt 0.5 oz / 15g</p>	<p>9853016 NDC 58133-111-05</p>	<p><b>Active Ingredient</b></p>	<p><b>Purpose</b></p>
			<p>Arnica Montana (2X H.P.U.S.)..... Pain</p> <p>*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.</p>	

<p><b>Uses:</b></p> <p>Temporarily relieves symptoms of pain and inflammation.</p>	<p><b>Warnings for external use only.</b> • When using this product avoid contact with eyes.</p> <p>If swallowed, get medical help or contact a Poison Control Center immediately. Test for allergy by rubbing small amount on skin first. Do not use if allergic to or hypersensitive to any ingredient. If condition worsens or does not improve consult a doctor.</p> <p>Stop use and ask a doctor • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develops.</p> <p>Keep all medicines out of reach of children.</p>
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<p><b>Directions:</b></p> <p>Apply to affected area 2 times daily - or as needed.</p>	<p><b>Other Ingredients:</b></p> <p>Petrolatum, Synthetic Beeswax, Isopropyl Palmitate, Menthol, Lanolin, Tocopheryl Acetate, Cocoa Nucleus (Coconut) Oil, Natural Flavor, Lavandula Angustifolia (Lavender) Oil, Glycerin, Chamomilla Recutita (Matricaria) Flower Extract, Butyrospermum Parkii (Shea) Butter, Mentha Piperita (Peppermint) Leaf Oil, Isopropyl Myristate, Aloe Barbados Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Camphor, Butylene Glycol, Stevia Rebaudiana Leaf/Stem Extract.</p>
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<b>HOMEOPATHIC LIP BALM</b>			
arnica montana ointment			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58 133-111
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	2 [hp_X] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
CAMPHOR LEAF OIL (UNII: 51D0RGY52V)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAVANDULA ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)	
BUTYROSPERMOL (UNII: 6SF0L0FL42)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
LANOLIN (UNII: 7EV65EAW6H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SIMMONDSIA CHINENSIS LEAF (UNII: 67G221EK95)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-111-05	15 g in 1 JAR; Type 0: Not a Combination Product	01/01/2015	
2	NDC:58133-111-01	5.5 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2015	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-111)