

**COLD SORE SUPPORT- allantoin, avobenzone, menthol, octinoxate and zinc oxide lipstick
MiraCell 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.

Active Ingredients

Allantoin 0.75%

Avobenzone 2.5%

Menthol 1.0%

Octinoxate 5.5%

Zinc Oxide 3.5%

Purpose

Skin Protectant

Sunscreen

External Analgesic

Sunscreen

Sunscreen

Uses:

- for the temporary relief of the pain and itching associated with fever blisters and cold sores
- provides moderate protection against sunburn
- temporarily protects chapped or cracked lips

Warnings: external use only

Directions:

- for cold sores/chapped lips, apply to lips with the first symptoms and as often as needed
- for sunscreen, reapply every 2 hrs

Inactive Ingredients: Beeswax, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea) Butter, Camellia Kissi Oil, Helianthus Annuus (Sunflower) Seed Oil, L-Lysine, Euphorbia Cerifera (Candelilla) Wax, Melissa Officinalis Leaf Oil (Lemon Balm), Tocopherol, Aloe Barbadensis Leaf Extract, Calendula Officinalis Flower Extract, Echinacea Angustifolia Leaf Extract, Mentha Piperita (Peppermint) Oil, Stevia Rebaudiana Extract, Natural Lemon Flavor

Questions? 1-800-748-5040 www.MiraCell.com

Keep out of reach of children.



Menthol 1.0%..... External Analgesic
Octinoxate 5.5%..... Sunscreen
Zinc Oxide 3.5%..... Sunscreen

Uses: • For the temporary relief of the pain and itching associated with fever blisters and cold sores • provides moderate protection against sunburn • temporarily protects chapped or cracked lips

Warnings: external use only

Directions: • for cold sores/chapped lips, apply to lips with the first symptoms and as often as needed • for sunscreen, reapply every 2 hrs

Inactive Ingredients: Beeswax, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea) Butter, Camellia Kissi Oil, Helianthus Annuus (Sunflower) Seed Oil, L-Lysine, Euphorbia Cerifera (Candelilla Wax), Melissa Officialis Leaf Oil (Lemon Balm), Tocopherol, Aloe Barbadensis Leaf Extract, Calendula Officialis Flower Extract, Echinacea Angustifolia Leaf Extract, Mentha Piperita (Peppermint) Oil, Stevia Rebaudiana Extract, Natural Lemon Flavor

Questions? 1-800-748-5040 www.MiraCell.com

Made in U.S.A.
Distributed by **MIRACELL**
1-800-748-5040
www.MiraCell.com



Allantoin & Menthol with L-Lysine & Lemon Balm

Temporary relief of the pain and
itching associated with cold sores.

0.16 oz / 4.5 g

MIRACELL®

Helps Your Skin Help Itself
Naturally

Cold Sore Support™

Cold Sore • Sunscreen • Lip Balm

Pure Botanical Extracts

with L-Lysine & Lemon Balm

Natural Lemon Flavor

SPF 15

Active Ingredients Allantoin 0.75%.....Skin Protectant Avobenzone 3.0%.....Sunscreen Menthol 1.0%...External Analgesic Octinoxate 6.0%.....Sunscreen Zinc Oxide 4.0%.....Sunscreen	Purpose Skin Protectant Sunscreen External Analgesic Sunscreen Sunscreen	 6 60403 25063 3
Warnings: external use only		

Made in U.S.A.
Distributed by: **MIRACELL**, Inc.
www.MiraCell.com

SPF 15
with **Allantoin & Menthol**
L-Lysine & Lemon Balm

Cold Sore Support™
Cold Sore • Sunscreen • Lip Balm

Pure Botanical Extracts
0.16 oz / 4.5 g
Natural Lemon Flavor

- Aloe Vera
- Camellia Kissi
- Shea butter
- Jojoba
- Echinacea
- Calendula

MIRACELL

Helps Your Skin Help Itself - Naturally

COLD SORE SUPPORT

allantoin, avobenzone, menthol, octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61223-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.75 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	3.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAMELLIA KISSII SEED OIL (UNII: 96HGN0T99A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

LYSINE (UNII: K3Z4F929H6)	
CANDELILLA WAX (UNII: WL0328HX19)	
LEMON BALM OIL (UNII: MJ76269K9S)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
STEVIA REBAUDIANA WHOLE (UNII: 6U422Y08O2)	
LEMON OIL (UNII: I9GRO824LL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 1223-10 1-21	1 in 1 BOX		
1	NDC:6 1223-10 1-11	4.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/01/2013	

Labeler - MiraCell Inc (150449945)

Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty.com		794053863	manufacture(6 1223-10 1)

Revised: 12/2013

MiraCell Inc