

AUBIO LIFE SCIENCES LIP- allantoin and lidocaine cream
Aubio Life Sciences LLC

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

Allantoin 0.50% (W/W)

Lidocaine 0.50% (W/W)

Purpose

skin protectant

external analgesic

Uses

- For the temporary relief of pain and Itching associated with cold sores and fever blisters
- Relieves dryness and softens cold sores and fever blisters

Warnings

For external use only

When using this product

- avoid contact with the eyes

Stop use and ask a doctor

- if condition worsens
- 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

Questions or comments?

Call Toll-free 1-844-My-Aubio (1-844-692-8246)

Weekdays 9am-5pm PT. If you are not completely satisfied, save receipt and remaining product and call us.

Directions

- Wash hands before and after applying gel
- Gently clean the affected area before applying
- Always rub gently into affected area
- Adults and children 2 years of age and older; apply to affected area not more than 3-4 times daily
- Children under 2 years of age, consult a doctor

Inactive Ingredients

Water (Aqua), Glycerin, Sarracenia Stalk/Flower/Seed Extract (and) Sarracenia Purpurea Leaf/Stalk/Flower/Seed Extract, Aloe Barbadensis Leaf Juice, Lavandula Angustifolia (Lavender) Flower Extract, Melissa Officinalis (Balm Mint) Extract, Dipotassium Glycyrrhizate, Phytosphingosine, Carbomer, Ceramide AP, Ceramide EOP, Ceramide NP, Cholesterol, Xanthan Gum, Sodium Hydroxide, Sodium Lauroyl Lactylate, Hexylene Glycol, Ethylhexylglycerin, Caprylyl Glycol, Phenoxyethanol

Other Information

- Recap after each use
- Store at room temperature
- Protect the product in this container from excessive heat and direct sun

Principal Display Panel - Blister Pack Label

Aubio™

Cold Sore

Treatment Gel

External Analgesic Lip Protectant

Ultra-effective formula with Botanicals

Relieves pain and itch

Cools and soothes

NET WT 3g (0.11 oz)

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AUBIO LIFE SCIENCES LIP

allantoin and lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70365-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	5 mg in 1 g
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Aloe vera Leaf (UNII: ZY81Z83H0X)	
Carbomer Interpolymer Type A (allyl sucrose crosslinked) (UNII: 59TL3WG5CO)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Caprylic Alcohol (UNII: NV1779205D)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Phytosphingosine (UNII: GIN46U9Q2Q)	
Sodium Lauroyl Lactylate (UNII: 7243K85WFO)	
Xanthan Gum (UNII: TTV12P4NEE)	
Cholesterol (UNII: 97C5T2UQ7J)	
Ceramide NP (UNII: 4370DF050B)	
3-Dehydroxy Ceramide 1 (UNII: CR0J8RN66K)	
Ceramide AP (UNII: F1X8L2B00J)	
Lavandula Angustifolia Flower (UNII: 19AHIRAF4M)	
Melissa Officinalis (UNII: YF70189L0N)	
Sarracenia Purpurea (UNII: FOP08H143P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70365-001-01	3 g in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part347	02/28/2016	
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Labeler - Aubio Life Sciences LLC (080080743)

Establishment

Name	Address	ID/FEI	Business Operations
KLEEN CONCEPTS		012989797	MANUFACTURE(70365-001) , LABEL(70365-001)

Revised: 1/2016

Aubio Life Sciences LLC