

COLD SORE TREATMENT- allantoin, lidocaine hydrochloride gel
Dimensional Merchandising 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.

COLD SORE TREATMENT GEL

Drug Facts

Active ingredients

Allantoin 0.5%

Lidocaine HCl 0.5%

Purposes

Lip 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

Allergy alert: Do not use if you have an allergy to Lidocaine or other "caine" ingredients.

Do not use on

- deep or puncture wounds • animal bites
- serious burns

When using this product avoid contact with the 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

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

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

Directions

- wash hands before and after applying gel
- gently clean the affected area before applying
- adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily

- children under 2 years of age: consult a doctor

Inactive ingredients

Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Alcohol, Carbomer, Sarracenia Leucophylla Flower/Leaf/Seed/Stalk Extract, Phenoxyethanol, Sodium Hydroxide, Caprylyl Glycol, Lavandula Angustifolia (Lavender) Flower Extract, Melissa Officinalis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Ethylhexylglycerin, Hexylene Glycol, Dipotassium Glycyrrhizate, Hypericum Perforatum Flower/Leaf Extract, Camellia Sinensis Leaf Extract, Acanthopanax Senticosus (Eleuthero) Root Extract

Other information

- recap after each use
- store at room temperature
- protect the product in this container from excessive heat and direct sun

Questions or comments?

Call Toll-Free **1-844-My-Aubio (1-844-692-8246)**

Monday-Friday 9am-5pm ET

relieves dryness soothes

EXTERNAL ANALGESIC/LIP PROTECTANT

Fast and effective temporary relief of pain and itching

Moisturizing formula with Aloe

Aubio™ Cold Sore Treatment Gel provides fast and effective temporary relief of cold sore pain and itching.

Patent Pending

Distributed by **Aubio Life Sciences, LLC**

Wixom, MI 48393

Aubio Life Sciences™

www.aubio.com



Packaging



Aubio™

Aubio™ Cold Sore Treatment Gel provides fast and effective temporary relief of cold sore pain and itching.

<p>Drug Facts</p> <p>Active Ingredients</p> <p>Allantoin 0.5%.....Lip Protectant Lidocaine HCl 0.5%.....External Analgesic</p> <p>Purposes</p> <p>Uses</p> <ul style="list-style-type: none"> for the temporary relief of pain and itching associated with cold sores and fever blisters relieves dryness and softens cold sores and fever blisters <p>Warnings</p> <p>For external use only</p> <p>Allergy alert: Do not use if you have an allergy to Lidocaine or other "caine" ingredients.</p> <p>Do not use on</p> <ul style="list-style-type: none"> deep or puncture wounds serious burns animal bites <p>When using this product avoid contact with the eyes.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> condition worsens symptoms persist for more than 7 days or clear up and occur again within a few days <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. →</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> wash hands before and after applying gel gently clean the affected area before applying adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily children under 2 years of age: consult a doctor <p>Other Information</p> <ul style="list-style-type: none"> recap after each use store at room temperature protect the product in this container from excessive heat and direct sun <p>Inactive Ingredients</p> <p>Water (Aqua), Glycerin, Aloe Barbadosensis Leaf Juice, Alcohol, Carbomer, Sarracenia Leucophylla Flower/Leaf/Seed/Stalk Extract, Phenoxethanol, Sodium Hydroxide, Caprylyl Glycol, Lavandula Angustifolia (Lavender) Flower Extract, Melissa Officinalis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Ethylhexylglycerin, Hexylene Glycol, Dipotassium Glycyrrhizate, Hypericum Perforatum Flower/Leaf Extract, Camellia Sinensis Leaf Extract, Acanthopanax Senticosus (Eleuthero) Root Extract</p> <p>Questions or comments?</p> <p>Call Toll-Free 1-844-My-Aubio (1-844-692-8246) Monday-Friday 9am-5pm ET</p>
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Patent Pending
Distributed by Aubio Life Sciences, LLC
Wixom, MI 48393

Aubio Life Sciences™
www.aubio.com

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COLD SORE TREATMENT

allantoin, lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61383-148
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ALCOHOL (UNII: 3K9958V90M)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
SARRACENIA PURPUREA (UNII: FOP08H143P)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
LICORICE (UNII: 61ZBX54883)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
GLICYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
ST. JOHN'S WORT (UNII: UFH8805FKA)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
ELEUTHERO (UNII: ZQH6VH092Z)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61383-148-01	1 in 1 BLISTER PACK	04/09/2018	
1	NDC:61383-148-11	3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/09/2018	

Labeler - Dimensional Merchandising Inc. (076693183)