

## **ZZIP COLD SORE TREATMENT- allantoin, dimethicone, menthol solution**

### **Zzip AG**

*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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### **Zzip Cold Sore Treatment**

#### **Drug Facts**

##### **☐Active Ingredients**

☐Allantoin 0.5%

Dimethicone 1%

Menthol 0.1%

#### **Purpose**

Cold sore/fever blister treatment

#### **Uses**

- Temporarily relieves the pain and itching associated with cold sores/fever blisters.
- Temporarily protects and helps relieve chapped or cracked lips.

#### **Warnings**

For external use only

#### **Do not use**

- if you are allergic to any ingredient in this product
- during pregnancy or breast-feeding.

#### **When using this product**

- avoid contact with eyes
- apply only to affected areas
- avoid applying directly inside your mouth
- do not share this product with anyone. This may spread infection.
- dispose cotton swab immediately after use
- discard after 1 month of opening the tube

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

- condition worsens
- symptoms last more than 7 days
- symptoms clear up and return in a few days.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

#### **▣adults and children 12 years or over:▣**

- Apply to affected area on face or lips at first sign (tingle) of cold sore/fever blister
- Open tube, saturate cotton swab with 8 drops of liquid
- Use the cotton swab to apply to affected area on face or lips. Do not touch the sore with your fingers. Continue for 3 seconds until the cold sore is completely covered and sealed.
- Dispose of cotton swab - do not reuse
- Wash hands before and after application.
- Apply 2 times daily, not to exceed 3 to 4 times daily until sore is healed

#### **▣children under 12 years: ask a doctor**

### **Other information**

Store at room temperature

Do not freeze

### **Inactive Ingredients**

Aloe Barbadosis, Calendula Officinalis Flower, Copper Sulfate, Demineralized water, Ethylhexylglycerin, Glycerin, Laureth-9, Maltodextrin, Opuntia Ficus Indica Stem, PEG-40 Hydrogenated Castor Oil, Pentylene Glycol, Phenoxyethanol, Propylene Glycol, Rhododendrum Ferrugineum, Trideceth-9.

### **Questions or comments?**

Call 1-800-257-7071 (English/Spanish) Weekdays

Visit us at [www.zzipusa.com](http://www.zzipusa.com)

### **Distributed in the USA by:**

GG Advisors, LLC

923 Haddonfield Rd., Suite 300

Cherry Hill, NJ 08002

1-800-257-7071

Switzerland developed by Zzip AG

Made in the Netherlands

### **Product labeling**

**Zzip. Zap. Gone**



Text ZZIP to 26786 for Promotions!

**Cold Sore Treatment  
Relieves Pain  
Halts Itching**



**Cold Sore Treatment  
Relieves Pain  
Halts Itching**



NETWT 0.1oz (3ml)

Allantoin, Dimethicone, Menthol  
Cold Sore/ Fever Blister Treatment/ Lip Protectant



# Zzip. Zap. Gone



Text ZZIP to 26786 for Promotions!

<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active ingredients</b> Allantoin 0.5% Dimethicone 1% } .....Cold sore/fever blister treatment Menthol 0.1%	<b>Directions</b>
<b>Purpose</b> Cold sore/fever blister treatment	<ul style="list-style-type: none"> <li>• <b>adults and children 12 years or over:</b> <ul style="list-style-type: none"> <li>• Apply to affected area on face or lips at first sign (tingle) of cold sore/fever blister.</li> <li>• Open tube, saturate cotton swab with 8 drops of liquid</li> <li>• Use the cotton swab to apply to affected area on face or lips. Do not touch the sore with your fingers. Continue for 3 seconds until the cold sore is completely covered and sealed.</li> <li>• Dispose of cotton swab - do not reuse.</li> <li>• Wash hands before and after application.</li> <li>• Apply 2 times daily, not to exceed 3 to 4 times daily until sore is healed.</li> </ul> </li> <li>• <b>children under 12 years:</b> ask a doctor</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>• Temporarily relieves pain and itching associated with cold sores/fever blisters</li> <li>• Temporarily protects and helps relieve chapped or cracked lips</li> </ul>	<b>Other information</b> <ul style="list-style-type: none"> <li>• Store at room temperature • Do not freeze</li> </ul>
<b>Warnings</b> For external use only	<b>Inactive ingredients</b>
<b>Do not use</b> • if you are allergic to any ingredient in this product • during pregnancy or breast-feeding	Aloe Barbadosis, Calendula Officinalis Flower, Copper Sulfate, Demineralized Water, Ethylhexyl glycerin, Glycerin, Laureth-9, Maltodextrin, Opuntia Ficus-Indica Stem, PEG-40 Hydrogenated Castor Oil, Pentylene Glycol, Phenoxyethanol, Propylene Glycol, Rhododendrum Ferrugineum, Trideceth-9.
<b>When using this product</b> • avoid contact with eyes • apply only to affected areas • avoid applying directly inside your mouth • do not share this product with anyone. This may spread infection. • dispose cotton swab immediately after use • discard after 1 month of opening the tube	<b>Questions or comments?</b> Call 1-800-257-7071 (English/Spanish) weekdays • Visit us at <a href="http://www.zzipusa.com">www.zzipusa.com</a>
<b>Stop use and ask a doctor if</b> • condition worsens • symptoms last more than 7 days • symptoms clear up and return in a few days	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	

## COLD SORE TREATMENT

### COLD SORE/ FEVER BLISTER TREATMENT/ LIP PROTECTANT

- TRANSPARENT
- HELPS TO PROVIDE PAIN AND ITCH RELIEF
- HELPS TO PROMOTE HEALING
- HELPS TO PROTECT AND RELIEVE CHAPPED OR CRACKED LIPS

#### What is Zzip®

Zzip® Zzip is a protective water resistant film layer forming liquid for treating cold sores

Zzip® forms a protective breathable layer over the cold sore and thereby helps to prevent spreading of the cold sore virus

Zzip® helps to relieve the painful itching and tingling associated with cold sores/fever blisters

Zzip® helps to promote healing of cold sores/fever blisters

## INSTRUCTIONS

If you feel an uncomfortable tingling, pain and or itching on your face or lips this could be the first sign of a cold sore, also called a fever blister. This could mean that the cold sore is starting to develop. Simply apply Zzip® to the affected area with a supplied cotton swab. Zzip® forms a protective layer over the cold sore preventing further spreading of the cold sore virus. Zzip® temporarily relieves the symptoms of pain and itching associated with cold sores/fever blisters and helps promote healing.

#### Warnings

**For external use only.**

#### Do not use

- if you are allergic to any ingredient in this product
- if you are pregnant or are breast-feeding
- discard 1 month after opening the tube

#### When using this product

- apply only to affected areas
- avoid contact with eyes
- avoid applying directly inside your mouth
- do not share this product with anyone. This may spread infection.
- dispose of cotton swab immediately after use

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

- condition worsens
- symptoms last more than 7 days
- symptoms 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 1-800- 257-7071

Store at room temperature. Do not freeze.

#### Distributed in the USA by:

GG Advisors, LLC  
923 Haddonfield Road, Suite 300  
Cherry Hill, NJ 08002 USA

Switzerland Developed by ZZIP AG  
Made in the Netherlands

Serious side effects associated with use of this product may be reported to this number: 1-800-257-7071

Visit us at [www.zzipusa.com](http://www.zzipusa.com)



#### Directions

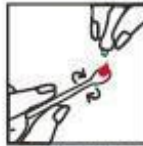
How to apply for

- adults and children 12 years or older:



WASH

1. Wash hands before application of Zzip® to help prevent the spread of the cold sore.



PREPARE

2. Remove cotton swab from plastic bag.
3. Open tube and saturate cotton swab with 8 drops of liquid.



APPLY

4. Use cotton swab to apply to affected area on face or lips. Do not touch sore with your fingers. Continue for 3 seconds until the sore is completely covered and sealed.



DISPOSE

5. Dispose of cotton swab. Do not re-use.



WASH

6. Wash hands after application of Zzip® to help prevent the spread of cold sore.

Apply 2 times daily not to exceed 3-4 times daily.

- children under 12 years: ask a doctor

#### Active Ingredients:

Allantoin 0.5%, Dimethicone 1%, Menthol 0.1%

#### Inactive Ingredients:

Aloe Barbadensis, Calendula Officinalis Flower, Copper Sulfate, Demineralized Water, Ethylhexylglycerin, Glycerin, Laureth-9, Maltodextrin, Opuntia Ficus-Indica Stem, PEG-40 Hydrogenated Castor Oil, Pentylene Glycol, Phenoxyethanol, Propylene Glycol, Rhododendrum Ferrugineum, Trideceth-9.

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## ZZIP COLD SORE TREATMENT

allantoin, dimethicone, menthol solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:700 19-100
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE (UNII: V5VD430 YW9)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
BASIC COPPER SULFATE (UNII: CUP529P5NS)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURETH-9 (UNII: 0AWH8BFG9A)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
OPUNTIA FICUS-INDICA STEM (UNII: MUD8892KHL)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
TRIDECETH-9 (UNII: X9HD79I514)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:700 19-100-00	3 mL in 1 TUBE; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/30/2015	

**Labeler** - Zzip AG (480040768)**Registrant** - Hen L Verpakkingen B.V. (407736821)**Establishment**

Name	Address	ID/FEI	Business Operations
Hen L Verpakkingen B.V.		407736821	manufacture(700 19-100)

## Establishment

Name	Address	ID/FEI	Business Operations
Flores Natural Cosmetic		404875689	pack(70019-100)

Revised: 7/2015

Zzip AG