

## **COLD SORE FEVER BLISTER TREATMENT- docosanol cream Topco Associates**

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**Docosanol Cream, 10%**

### ***Active ingredient***

Docosanol 10%

### ***Purpose***

Cold sore/fever blister treatment

### ***Uses***

- treats cold sores/fever blisters on the face or lips
- shortens healing time and duration of symptoms:
  - tingling, pain, burning, and/or itching

### **Warnings**

**Allergy Alert:** This product may cause a severe allergic reaction. Symptoms may include:

- hives
- facial swelling
- wheezing/difficulty
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

### **For external use only**

### **Do not use**

- if you are allergic to any ingredient in this product

### **When using this product**

- apply only to the affected areas
- do not use in or near the eyes
- avoid applying directly inside your mouth
- do not share this product with anyone. This may spread the infection.

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

- your cold sore gets worse or the cold sore is not healed within 10 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:**
  - wash hands before and after applying cream
  - apply to affected area on the face or lips at the first sign of cold sore/fever blister (tingle).
  - early treatment ensures the best results
  - rub in gently but completely
  - use 5 times a day until healed
- **children under 12 years:** ask a doctor

### ***Other information***

- store at 20° to 25°C (68° to 77°F)
- do not freeze

### ***Inactive ingredients***

benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate, sucrose stearate

### **Questions or comments?**

Call toll free **1-888-423-0139**

### **Principal Display Panel**

†COMPARE TO THE ACTIVE INGREDIENT IN ABREVA®

Cold Sore Treatment

COLD SORE/FEVER BLISTER TREATMENT

DOCOSANOL CREAM, 10%

- Only FDA Approved Medicine to Shorten Healing Time\*
- Cold Sore Treatment

NET WT 2 g (0.07 oz)

\*Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

**RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS**

DISTRIBUTED BY  
 TOPCO ASSOCIATES LLC  
 ITASCA, IL 60143

**Package Label**



**Thank you for purchasing Docosanol 10% Cream.** We hope that since Docosanol Cream has been demonstrated to shorten the healing time of cold sores, it helps you look and feel better faster. Please follow insert directions for proper use and refer to the information below.

**You Are Not Alone**  
 An estimated one-in-five Americans is affected by cold sores each year. Most people who experience them get two to three cold sore outbreaks each year. Just before and during an outbreak, the cold sore infection can be easily passed on to others. It is especially important to be aware of early warning signs that a cold sore is coming, and to be sure to avoid close physical contact when you have one.

**Getting to the Root of the Problem**  
 A blister, or cluster of blisters around your mouth, is caused by the cold sore virus. After the cold sore has healed, the virus stays dormant in your body but can be reactivated by everyday triggers like stress, sunlight, extreme hot or cold weather, colds and flu, lack of sleep, or menstruation.

**The Sooner, the Better**  
 A typical cold sore outbreak can last as long as seven to ten days. The sooner you begin using Docosanol Cream, 10% the more effective the medicine will be. So for best results, use Docosanol Cream, 10% at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.  
 Docosanol Cream, 10% is different from other Over-The-Counter cold sore products. Only Docosanol Cream, 10% contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including tingling, pain, itching and burning.

Scan here for more information or QUESTIONS? 1-888-423-0139  
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 DISTRIBUTED BY TOPCO ASSOCIATES LLC  
 QUALITY GUARANTEED  
 distributor of Abreva®.  
 Holdings (US) LLC,  
 Consumer Healthcare  
 by GlaxoSmithKline  
 manufactured or distributed  
 "This product is not  
 time and duration of symptoms.  
 by the FDA to shorten healing  
 the only OTC medicine approved  
 Docosanol Cream, 10% contains

call 1-888-423-0139  
 www.topcarebrand.com  
 topcare@topco.com

PLD-483CA F000901  
 0 36800 4964 1 5

**RETURN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS.**

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b>          Docosanol 10%. Cold sore/fever blister treatment.</p> <p><b>Purpose</b>          Treats cold sore/fever blisters on the face or lips.</p> <p><b>Uses</b>          ■ shortens healing time and duration of symptoms;          ■ tingling, pain, burning, and/or itching.</p> <p><b>Warnings</b>          This product may cause a severe allergic reaction. Symptoms may include: ■ hives ■ facial swelling ■ wheezing/difficulty breathing ■ shock ■ rash</p> <p><b>For external use only</b>          ■ If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b>          ■ if you are allergic to any ingredient in this product.</p> <p><b>When using this product</b>          ■ apply only to the affected area          ■ do not use in or near the eyes          ■ avoid applying directly inside your mouth          ■ do not share this product with anyone. This may spread the infection.</p> <p><b>Stop use and ask a doctor if</b>          ■ your cold sore gets worse or the cold sore is not healed within 10 days</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b>          ■ adults and children 12 years or over:          ■ apply to affected area on the face or lips at the first sign of cold sore/fever blister (tingle)          ■ early treatment ensures the best results          ■ rub in gently but completely          ■ use 5 times a day until healed          ■ children under 12 years: ask a doctor</p> <p><b>Other information</b>          ■ store at 20°-25°C (68°-77°F) ■ do not freeze</p> <p><b>Inactive ingredients</b>          benzyl alcohol, light mineral oil, propylene glycol, purified water, sorbic acid, sorbic ester, sorbic stearate</p> <p><b>Questions or comments?</b>          Call toll free 1-888-423-0139</p>
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**Frequently Asked Questions:**

**Who can use Docosanol Cream, 10%?**  
 Adults and children 12 years and over can use Docosanol Cream, 10%.

**How often can I apply Docosanol Cream, 10%?**  
 Docosanol Cream, 10% should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.

**Can I apply cosmetics on top of Docosanol Cream, 10%?**  
 Yes, cosmetics such as lipstick may be applied over Docosanol Cream, 10%. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream, 10%.

**TOPCARE HEALTH Cold Sore Fever Blister Treatment**

# COLD SORE FEVER BLISTER TREATMENT

docosanol cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-818
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOCOSANOL</b> (UNII: 9G1OE216XY) (DOCOSANOL - UNII:9G1OE216XY)	DOCOSANOL	100 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCROSE DISTEARATE (HLB 5)</b> (UNII: 33X4X4B90S)	
<b>SUCROSE STEARATE</b> (UNII: 274KW0050M)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76162-818-07	1 in 1 PACKAGE	12/31/2023	06/30/2028
1		2 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA212385	12/31/2023	06/30/2028

**Labeler** - Topco Associates (006935977)

