

**ABREVA- docosanol cream**  
**Haleon US Holdings LLC**

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**Drug Facts**

**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 breathing
- 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 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 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 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 °-25 °C (68 °-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 **1-877-709-3539**

### ***Additional information***

**\*ABREVA contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.**

**Retain this insert for full product uses, directions and warnings.**

If you are not completely satisfied, save receipt and remaining product, and call us at 1-877-709-3539.

**Thank you for purchasing ABREVA.** We hope that since ABREVA shortens 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 ABREVA, the more effective the medicine will be. So for best results, use ABREVA at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.

### **Frequently Asked Questions:**

#### **How is ABREVA different from the Over-The-Counter cold sore remedies I have already been using?**

Abreva contains 10% docosanol, the only FDA approved non-prescription ingredient that can actually shorten healing time and the duration of symptoms including tingling, pain, itching, and burning. The sooner you start using ABREVA, the sooner you can begin healing your cold sore. No other Over-The-Counter cold sore product heals your cold sore faster.

#### **Who can use ABREVA?**

Adults and children 12 years and over can use ABREVA.

#### **How often can I apply ABREVA?**

ABREVA 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 ABREVA?**

Yes, cosmetics such as lipstick may be applied over ABREVA. 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 ABREVA.

### **For More Information:**

Call us at 1-877-709-3539

**Abreva**  
**DOCOSANOL 10% CREAM**  
***COLD SORE/FEVER BLISTER TREATMENT***

### **Principal Display Panel**

**abreva**

**DOCOSANOL 10% CREAM**

***Cold Sore/Fever Blister Treatment***

**Cold Sore Treatment**

**Beauty Unaltered**

**NET WT**

**2g (0.07 oz)**

1000771



## **ABREVA**

docosanol cream

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOCOSANOL</b> (UNII: 9G10E216XY) (DOCOSANOL - UNII:9G10E216XY)	DOCOSANOL	100 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<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</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**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0200-01	2 g in 1 TUBE; Type 0: Not a Combination Product	03/19/2010	
2	NDC:0135-0200-03	2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/19/2010	
3	NDC:0135-0200-04	2 in 1 PACKAGE	03/19/2010	02/29/2020
3		2 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0200-05	2 in 1 PACKAGE	07/06/2017	
4		2 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:0135-0200-06	3 in 1 PACKAGE	01/02/2024	
5		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020941	03/19/2010	

**Labeler** - Haleon US Holdings LLC (079944263)

