

**DOCOSANOL- docosanol cream**  
**H2-Pharma, LLC**

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**DOCOSANOL**

***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 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°-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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**  
Montgomery, AL 36117

### **PRINCIPAL DISPLAY PANEL - 2 g Tube Label**

NDC 61269-881-35

†Compare to the active  
ingredient in Abreva®

Docosanol  
Cream, 10%

Cold sore/fever blister treatment

Only FDA approved medicine  
to shorten healing time\*

Cold sore treatment

Net wt. 2 g  
(0.07 oz)

H<sup>2</sup> pharma





NDC 61269-881-35  
†Compare to the active  
ingredient in Abreva®

# Docosanol Cream, 10%

**Cold sore/fever blister treatment**

Only FDA approved medicine  
to shorten healing time\*

Cold sore treatment

**Net wt. 2 g  
(0.07 oz)**



## **Drug Facts**

### **Active ingredient**

Docosanol 10%.....Cold sore/fever blister treatment

### **Purpose**

**Uses** — treats cold sore/fever blisters on the face or lips

## **Drug Facts (continued)**

**Keep out of reach of children.**

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

**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 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

### 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°-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 1-877-753-3935 Monday-Friday 9AM-5PM EST



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

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

Distributed by: **H2-Pharma, LLC**  
Montgomery, AL 36117  
www.h2-pharma.com

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

## DOCOSANOL

docosanol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61269-881
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCOSANOL</b> (UNII: 9G1OE216XY) (DOCOSANOL - UNII:9G1OE216XY)	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: 274KW0O50M)				
<b>Product Characteristics</b>				
<b>Color</b>		WHITE	<b>Score</b>	
<b>Shape</b>			<b>Size</b>	
<b>Flavor</b>			<b>Imprint Code</b>	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61269-881-35	2 g in 1 TUBE; Type 0: Not a Combination Product	04/10/2025	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA		ANDA212385	04/10/2025	

**Labeler** - H2-Pharma, LLC (028473634)