

**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 (1-800-222-1222) 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 Bottle Package**

NDC 61269-989-37

†Compare to the active ingredient in Abreva®

Docosanol

Cream 10%

Cold sore/fever blister treatment

Portable convenient pump

Only FDA-approved medicine to shorten healing time\*

Cold sore treatment

Net wt. 2 g  
(0.07 oz)

H<sup>2</sup> pharma



NDC 61269-989-37  
†Compare to the active ingredient in Abreva®

# Docosanol Cream 10%

## Cold sore/fever blister treatment

Portable convenient pump



Only FDA-approved medicine to shorten healing time\*  
Cold sore treatment

Net wt. 2 g  
(0.07 oz)



PLD-A729A F0008286

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www.h2-pharma.com

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

### NO COATING

\*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 GSK Consumer Healthcare, distributor of Abreva®.



## DOCOSANOL

docosanol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61269-989
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCROSE DISTEARATE (UNII: 33X4X4B90S)	
SUCROSE STEARATE (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:61269-989-37	1 in 1 PACKAGE	07/18/2023	
1		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
ANDA	ANDA212385	07/18/2023	

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

Revised: 7/2023

H2-Pharma, LLC