

**DOCOSANOL- docosanol cream**  
**Leader/ Cardinal Health 110, Inc.**

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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 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° 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 **1-866-210-9797** Monday-Friday 9AM-6PM EST

**PRINCIPAL DISPLAY PANEL**

**TUBE PACK**

**NDC 70000-0672-1**

**Docosanol Cream, 10%**

Compare to the active ingredient in Abreva®\*

Cold Sore/Fever Blister Treatment

Non-prescription Medicine to Shorten Healing Time\*\*

Cold Sore Treatment

For Topical Use Only

NET WT 2g (0.07 oz)

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

\*\*Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

**Distributed by:**

**CARDINAL HEALTH,**

DUBLIN, OHIO 43017

Code No.: GUJ/DRUGS/G/25/2216

Made in India



**Thank you for purchasing Docosanol Cream, 10%.**  
 We hope that since Docosanol Cream 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 Docosanol Cream, the more effective the medicine will be, so for best results, use Docosanol Cream at the very start of the cold sore – when you feel the first sign of the tingle, redness, bump, or itch. Docosanol Cream is different from other over-the-counter cold sore products. Only Docosanol Cream, contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including, tingling, pain, itching, and burning.

**Frequently Asked Questions:**

**How is Docosanol Cream different from the over-the-counter cold sore remedies I have already been using?**

Docosanol Cream is a non-prescription cold sore medicine that can actually shorten healing time and the duration of symptoms. The sooner you start using Docosanol Cream, the sooner you can begin healing your cold sore.

**Who can use Docosanol Cream?**

Adults and children 12 years and over can use Docosanol Cream.

**How often can I apply Docosanol Cream?**

Docosanol Cream 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?**

Yes, cosmetics such as lipstick may be applied over Docosanol Cream. 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.

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

**Drug Facts** (continued)

**Active ingredient**  
 Docosanol 10%..... Cold sore/fever blister treatment

**Purpose**  
 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 the first sign of cold sore/fever blister (tingle)  
 • apply treatment 5 times a day until healed completely  
 • only treatment ensures the best results

**Warnings**  
 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.  
 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  
 Call 1-866-210-9787

**Other information**  
 • store at 20° to 25° C (68° to 77° F)  
 • do not freeze  
 Inactive ingredients  
 benzyl alcohol, light mineral oil, polyethylene glycol, purified water, sacrosulic acid, sorbic stearate.

**Questions or comments?**  
 Monday-Friday 9AM-6PM EST  
 Call 1-866-210-9787

**Drug Facts**  
 Contains the only non-prescription cold sore 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®.  
 ††† Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

PKCP16106 03/2024  
 Code No.: 6UJ/DHSS/25/2216  
 100% Money Back Guarantee  
 Return to place of purchase.

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 www.myls.com 1-800-200-6515 Made in India  
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Lot & Code area  
 No Varnish Area  
 37 x 16 mm

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**PUMP PACK**

**NDC 70000-0743-1**

**Docosanol Cream, 10%**

Compare to the active ingredient in Abreva®\*

Cold Sore/Fever Blister Treatment

Non-Prescription Medicine to Shorten Healing Time\*\*

Cold Sore Treatment

For Topical Use Only

NET WT 2g (0.07 oz)

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

\*\*Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

**Distributed by:**

**CARDINAL HEALTH,**

DUBLIN, OHIO 43017

Code No.: GUJ/DRUGS/G/25/2216

Made in India

**LEADER<sup>2</sup>**

NDC 70000-0745-1

## Docosanol Cream, 10%

Cold Sore/Fever Blister Treatment

Portable  
Convenient  
Pump

Non-Prescription  
Medicine to Shorten  
Healing Time\*\*

Cold Sore Treatment  
For Topical Use Only

Read inside fold-out  
for full details.

**COMPARE TO  
THE ACTIVE  
INGREDIENT  
IN ABREVA<sup>®</sup>\*\***

100% Money  
Back Guarantee

NET WT 2 g (0.07 OZ)

**Thank you for purchasing Docosanol Cream, 10%.**

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, the more effective the medicine will be, so for best results, use Docosanol Cream at the very start of the cold sore – when you feel the first sign of the tingle, redness, bump, or itch. Docosanol Cream is different from other over-the-counter cold sore products. Only Docosanol Cream contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including tingling, pain, itching, and burning.

Return to place of purchase.

100% Money Back Guarantee

DISTRIBUTED BY CARDINAL HEALTH, LOUISIN, OHIO 45070  
www.leader.com 1-800-200-6373  
Made in India

No Varnish Area  
37 x 13 mm

Code No.: GUJRHUGS/6/25/216  
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08/2025

\*This product is not manufactured or distributed by SSK Consumer Healthcare, distributor of Abreva.  
\*\*Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

<p><b>Questions or comments?</b> Call 1-866-210-9797 Monday-Friday 9AM-6PM EST</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 • do not share the product with anyone. This may spread infection. • avoid applying directly inside your mouth. • do not use in or near the eyes • apply only to affected areas. • avoid alcohol, light mineral oil, propylene glycol, purified water, sucrose stearate, benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose stearate.</p>
<p><b>Inactive ingredients</b> benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose stearate, do not freeze.</p>	<p><b>For external use only</b> Do not use • if you are allergic to any ingredient in this product. Right away: • wheezing/difficulty breathing • shock • rash If an allergic reaction occurs, stop use and seek medical help. This product may cause a severe allergic reaction. Symptoms may include • hives • facial swelling • wheezing/difficulty breathing • shock • rash</p>
<p><b>Other information</b> • store at 20° to 25°C (68° to 77°F) • use 5 times a day until healed • rub in gently but completely • do not freeze</p>	<p><b>Warnings</b> 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: • tingling, pain, burning, and/or itching • shortens healing time and duration of symptoms; • treats cold sore/fever blisters on the face or lips</p>
<p><b>Directions</b> • adults and children 12 years or over: • apply hands attached area on face or lips at the first sign of cold sore/fever blister (tingle). • wash hands attached area on face or lips after applying cream</p>	<p><b>Active ingredient</b> Docosanol 10% Cold sore/fever blister treatment.</p>
<p><b>Drug Facts (continued)</b> Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away (1-800-222-1222).</p>	<p><b>Purpose</b> Docosanol 10% Cold sore/fever blister treatment.</p>

Retain this insert for full product uses, directions, and warnings.  
Press pump completely about 6 to 8 times to get first dose.

0 6041776 REV 08/25 96299 14545 8

**How to use your Docosanol Cream Pump:** For adults and children 12 years and over, Docosanol Cream 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. If you wish, you can apply cosmetics such as lipstick over Docosanol Cream. 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.






**STEP 1:** Wash your hands before and after treating the cold sore.

**STEP 2:** Remove cap and press pump firmly. When first used, expect to press pump completely about 6 to 8 times before obtaining first dose.

**STEP 3:** Rub in gently but completely 5 times a day until healed for maximum of 10 days.

**STEP 4:** Place cap back on pump after each use.

For more information: Call us at 1-866-210-9797

<b>DOCOSANOL</b>			
docosanol cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0672
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

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

  

Inactive Ingredients		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			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0672-1	1 in 1 PACKAGE	05/22/2024	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215839	05/22/2024	

DOCOSANOL			
docosanol cream			

  

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0743
Route of Administration	TOPICAL		

  

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DOCOSANOL (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: 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:70000-0743-1	1 in 1 PACKAGE	12/25/2025	
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	ANDA215839	12/25/2025	

**Labeler** - Leader/ Cardinal Health 110, Inc. (063997360)

**Registrant** - Alembic Pharmaceuticals Limited (650574663)

## Establishment

Name	Address	ID/FEI	Business Operations
Contract Packaging Resources, Inc.		960203917	PACK(70000-0672, 70000-0743)

## Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(70000-0672, 70000-0743) , ANALYSIS(70000-0672, 70000-0743)