

DOCOSANOL- docosanol cream
CVS Pharmacy, Inc.

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 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 ingredient

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**PUMP PACK****NDC 51316-763-64****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:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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Mfg. License No.: G/25/2216



Thank you for purchasing CVS Health® 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.

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

Drug Facts (continued)

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 and over:
 - wash hands before and after applying cream
 - apply to affected area on lips or lips at the first sign of cold sore/fever blister (tingle)
 - early treatment ensures the best results
 - this is 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, polyethylene glycol, purified water, sucrose disphosphate, sucrose stearate.

Warnings

- tingling, pain, burning, and/or itching
- This product may cause a severe allergic reaction. Symptoms may include:
 - hives
 - facial swelling
 - breathing difficulty
- If an allergic reaction occurs, stop use and seek medical help right away.

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

Questions or comments?

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

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PKCPT16088 1/2023
#34045T

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How to use your Docosanol Cream Pump: For adults and children 12 years and over, Docosanol Cream can 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

PRINCIPAL DISPLAY PANEL

TUBE PACK

NDC 51316-763-04

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

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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.

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).
• 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

Warnings
This product may cause a severe allergic reaction. Symptoms may include:
• hives • facial swelling
• wheezing/difficulty breathing • shock • rash
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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

Inactive ingredients
glycol purified water, light mineral oil, polyurethane, sucrose stearate.

Other information
• do not freeze
• store at 20° to 25° C (68° to 77° F)

Questions or comments?
Call 1-866-210-9197 Monday-Friday 9AM-6PM EST

#355505
PKCF16089 1/2023
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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 sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream.

PRINCIPAL DISPLAY PANEL

TUBE PACK

NDC 51316-763-02

Docosanol Cream, 10%

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Non-prescription Medicine to Shorten Healing Time**

Cold Sore Treatment

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DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-763
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
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:51316-763-04	1 in 1 PACKAGE	01/06/2023	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51316-763-64	1 in 1 PACKAGE	01/06/2023	
2		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:51316-763-02	1 in 1 PACKAGE	01/06/2023	
3		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	01/06/2023	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Alembic Pharmaceuticals Limited (650574663)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Packaging Resources, Inc.		960203917	PACK(51316-763)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(51316-763) , ANALYSIS(51316-763)

Revised: 12/2023

CVS Pharmacy, Inc.