

**COLD SORE FEVER BLISTER TREATMENT- docosanol cream
P & L Development, LLC**

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
- 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

Principal Display Panel

†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)

*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 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

Distributed by:
PL Developments
 200 Hicks Street
 Westbury, NY 11590


Package Label

NDC 59726-877-07
*Compare to the active ingredient in Abreva®

Docosanol Cream, 10%

Cold sore/fever blister treatment

Portable convenient pump



NET WT 2 g (0.07 oz)


FDA #47954 F000370

Distributed by:
 PL Developments
 200 Hicks Street
 Westbury, NY 11590



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

NO COATING

This product is not manufactured or distributed by Genovese-Hinkins Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

Drug Facts	<p>Keep out of reach of children.</p> <p>If swallowed, get medical help or contact a Poison Control Center 1-800-222-1222 (1-222) right away.</p>
Active ingredient	Docosanol 10% Cold sore/fever blister treatment
Purpose	Cold sore/fever blister treatment
Uses	<ul style="list-style-type: none"> ■ treats cold sore/fever blisters on the face or lips ■ shortens healing time and duration of symptoms. ■ tingling, pain, burning, and/or itching
Warnings	<p>Caution: This product may cause a severe allergic reaction.</p> <p>Symptoms may include: ■ hives ■ facial swelling ■ rash ■ itching, pain, burning, and/or itching</p> <p>Do not use ■ if you are allergic to any ingredient in this product</p>
Other information	<p>■ early treatment ensures the best results</p> <p>■ use in gently but completely</p> <p>■ use 5 times a day until healed</p> <p>■ children under 12 years: ask a doctor</p>
Inactive ingredients	<p>benzyl alcohol, light mineral oil, propylene glycol, purified water, sorbic disorbate, sucrose stearate</p>
Questions or comments?	<p>Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>

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, 10%, the more effective the medicine will be. So for best results, use Docosanol Cream, 10% at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.

Docosanol Cream, 10% is different from other over-the-counter cold sore products. Only Docosanol Cream, 10% contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including tingling, pain, itching and burning.

How to use your Docosanol Cream, 10% Pump

- For adults and Children 12 years and over
- Docosanol Cream, 10% 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, 10%. 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, 10%.

Press Pump completely about 6-8 times to get first dose.



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 6-8 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 1-877-753-3935

PL DEVELOPMENTS Cold Sore Fever Blister Treatment

COLD SORE FEVER BLISTER TREATMENT

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-877
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:59726-877-07	2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208754	12/31/2023	

Labeler - P & L Development, LLC (800014821)