

COLD SORE FEVER BLISTER TREATMENT- docosanol cream Safeway, 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
- 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° 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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO Abreva® active ingredient**

COLD SORE CREAM

DOCOSANOL CREAM10%

COLD SORE & FEVER BLISTER TREATMENT

ONLY FDA-APPROVED MEDICINE TO SHORTEN HEALING TIME*

COLD SORE TREATMENT

Portable convenient pump

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 Haleon group of companies

distributor of Abreva®.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

DISTRIBUTED BY:

BETTER LIVING BRANDS LLC

P.O. BOX 99

PLEASANTON, CA 94566-0009

Package Label



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

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

Habeon group of companies, distributor of Abreva®. Scan here for more information.

SmartLabel™

Product of India
DISTRIBUTOR BY: BETTER LIVING BRANDS LLC
P.O. BOX 99
FLEMINGTON, CA 94566-0099
1-888-723-3923

S0683 R024313

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PLD-AZ9A F009157

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

| | |
|-------------------------------|---|
| Drug Facts | Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. |
| Active ingredient | Docosanol 10% Cold sore/fever blister treatment |
| Purpose | Docosanol 10% 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 | ■ If an allergic reaction occurs, stop use and seek medical help right away. ■ Symptoms may include: ■ hives ■ facial swelling ■ rash ■ itching, burning, and/or itching |
| 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 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 | benzoyl alcohol, light mineral oil, propylene glycol, purified water, sucrose disaccharate, sucrose stearate |
| Questions or comments? | Call 1-877-753-3935 Monday-Friday 9AM-5PM EST |

SIGNATURE SELECT Cold Sore & Fever Blister Treatment

COLD SORE FEVER BLISTER TREATMENT

docosanol cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-605 |
| Route of Administration | 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 (HLB 5) (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:21130-605-07 | 2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 07/31/2024 | 12/31/2026 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA212385 | 07/31/2024 | 12/31/2026 |

Labeler - Safeway, Inc. (009137209)

Revised: 12/2025

Safeway, Inc.