

COLD SORE FEVER BLISTER TREATMENT- docosanol cream
Rugby Laboratories, 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 the active ingredient in Abreva®†

Docosanol Cream 10%

Cold Sore/Fever Blister Treatment 10%

Non-prescription medicine to shorten healing time*

Cold sore treatment

For Topical Use Only

NET WT 2 g (0.07 oz)

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

* Non-prescription cold sore medicine to shorten healing time and duration of symptoms.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS


Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

www.majorpharmaceuticals.com

Package Label



NDC 0536-1379-04
Compare to the active ingredient in Abreva™

Docosanol Cream 10%

Cold Sore/Fever Blister Treatment

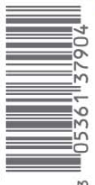
10%

Non-prescription Medicine to Shorten Healing Time*
Cold Sore Treatment For Topical Use Only

NET WT 2g (0.07 oz)

www.majorpharmaceuticals.com
(800) 616-2471
Indianapolis, IN 46268
Distributed by:
RUGBY LABORATORIES
SKS Consumer Healthcare, distributor of Abreva™

PLD-A61A FD006430 Rev.12/22 R-58 Re-order No. 37138



0536137904 9

Drug Facts (continued)

Active Ingredient
Docosanol 10%
Cold sore/fever blister treatment

Purpose
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:
■ 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

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 dispersant, sucrose stearate

Questions or Comments?
Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

Docosanol Cream, 10%

Thank you for purchasing Docosanol Cream. 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.

RUGBY Cold Sore Fever Blister Treatment

COLD SORE FEVER BLISTER TREATMENT

docosanol cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1379 |
| 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 (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:0536-1379-04 | 1 in 1 PACKAGE | 01/01/2023 | |
| 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 | ANDA208754 | 01/01/2023 | |

Labeler - Rugby Laboratories, Inc. (079246066)

