

DOCOSANOL - docosanol cream
KROGER COMPANY

Drug Facts

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 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.

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 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 and sucrose stearate

Questions or comments?

call **1-800-632-6900**

Additional information

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

Retain insert for full product uses, directions and warnings.

**DISTRIBUTED BY
THE KROGER CO., CINCINNATI, OHIO 45202**

MADE IN INDIA
‡OUR PHARMACIST RECOMMENDED

Code: TS/DRUGS/58039/2020

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 the only FDA approved 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.

For more information:

Call us at 1-800-632-6900

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Label 10% (2 g Tube)

NDC 30142-286-02

Kroger®
health

Docosanol Cream 10%
COLD SORE/FEVER
BLISTER TREATMENT

NET WT 0.07 oz (2 g)

For Topical Use Only

Retain insert for full product uses, directions and warnings.



NDC 30142-286-02

Docosanol Cream 10%

**COLD SORE/FEVER
BLISTER TREATMENT** | **NET WT 0.07 OZ (2 g)**

For Topical Use Only

Retain insert for full product uses, directions and warnings.

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

MADE IN INDIA

†OUR PHARMACIST RECOMMENDED

Code: TS/DRUGS/58039/2020

P4200010 LM-5843

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Square Blister Card Label 10% (2 g Tube)

NDC 30142-286-02

Kroger®
health

COMPARE TO THE ACTIVE INGREDIENT
IN ABREVA® COLD SCORE CREAM†

Docosanol Cream 10%
**Cold Sore/
Fever Blister
Treatment**

Non-Prescription
Medicine to
Shorten
Healing Time*

**COLD SORE TREATMENT
FOR TOPICAL USE ONLY**

**NET WT
0.07 oz (2 g)**

DISTRIBUTED BY THE KROGER CO. *Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.
 CINCINNATI, OHIO 45202
 MADE IN INDIA
 OUR PHARMACIST RECOMMENDED
 Our Brands. Our Guarantee. Love It or Your Money Back. www.kroger.com

NDC 30142-286-02



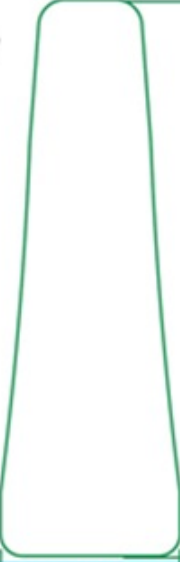
COMPARE TO THE ACTIVE INGREDIENT IN ABREVA® COLD SORE CREAM†

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

Drug Facts	Purpose
Active ingredient 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	Drug Facts (continued) 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
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.	Other information • store at 20° to 25°C (68° to 77°F). • do not freeze
For external use only Do not use • if you are allergic to any ingredient in this product	Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate
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.	Questions or comments? Call 1-800-632-6900
Stop use and ask a doctor if • your cold sore gets worse or the cold sore is not healed within 10 days.	†Abreva® is a registered trademark of Haleon UK IP Limited.
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. →	0 4 1260 02236 4 Code: TS/DRUGS/58039/2020 LM-5812 P4100403
	Lot: NVZ Exp.:

Docosanol Cream 10%

Cold Sore/
Fever Blister
Treatment
Non-Prescription
Medicine to
Shorten
Healing Time*



COLD SORE TREATMENT FOR TOPICAL USE ONLY | **NET WT 0.07 OZ (2 g)**

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Clamshell Blister Card label 10% (2 g Tube)

NDC 30142-286-04



COMPARE TO THE ACTIVE INGREDIENT IN ABREVA® COLD SCORE CREAM†

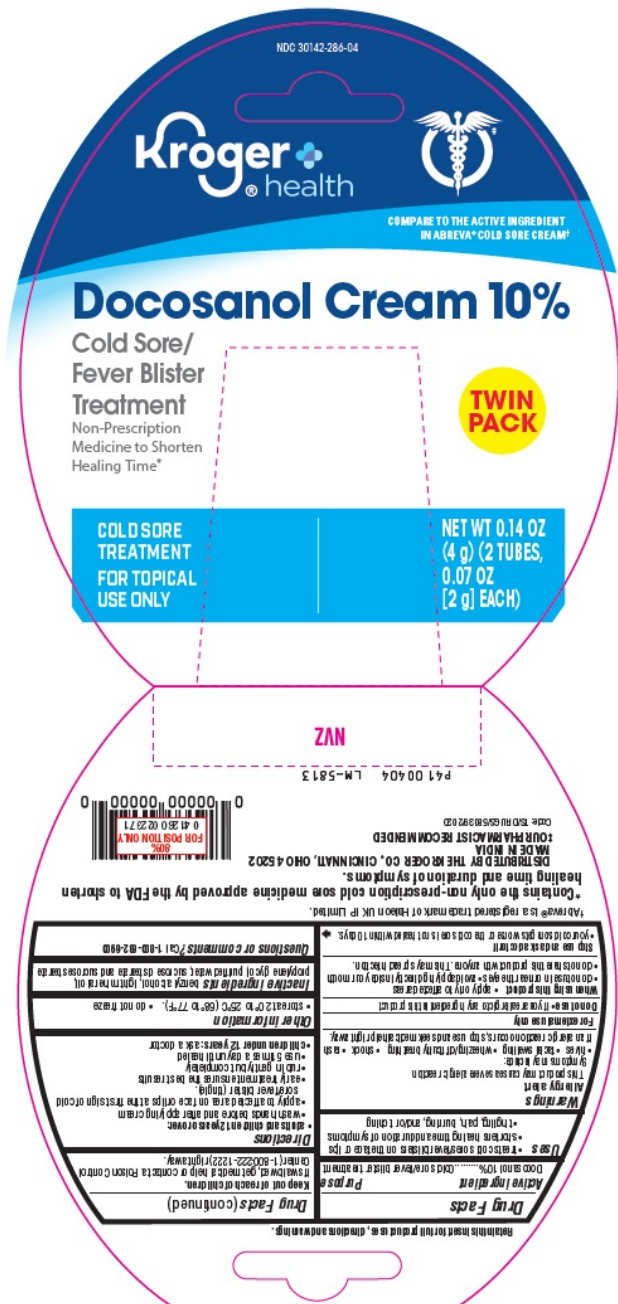
Docosanol Cream 10%
**Cold Sore/
 Fever Blister
 Treatment**
 Non-Prescription

**TWIN
 PACK**

Medicine to
Shorten
Healing Time*

**COLD SORE
TREATMENT
FOR TOPICAL
USE ONLY**

**NET WT 0.14 OZ
(4 g) (2 TUBES,
0.07 OZ
[2 g] EACH)**



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 the only FDA approved 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.

For more information:

Call us at 1-800-632-6900

Our Brands. Our Guarantee.
Love It or Your Money Back.
www.kroger.com

DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-286
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: 059QF0KOOR)	
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:30142-286-02	1 in 1 PACKAGE	06/26/2024	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:30142-286-04	2 in 1 PACKAGE	06/26/2024	
2		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	ANDA217090	06/26/2024	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		878100017	ANALYSIS(30142-286) , MANUFACTURE(30142-286)