

ABREVA- docosanol cream

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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 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°-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 toll-free **1-877-709-3539**

Additional information

***ABREVA contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.**

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

If you are not completely satisfied, save receipt and remaining product, and call us at 1-877-709-3539.

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GSK Consumer Healthcare

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Thank you for purchasing ABREVA. We hope that since ABREVA 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 ABREVA, the more effective the medicine will be. So for best results, use ABREVA at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.

Frequently Asked Questions:

How is ABREVA different from the Over-The-Counter cold sore remedies I have already been using?

Abreva contains 10% docosanol, the only FDA approved non-prescription ingredient that can actually shorten healing time and the duration of symptoms including tingling, pain, itching, and burning. The sooner you start using ABREVA, the sooner you can begin healing your cold sore. No other Over-The-Counter cold sore product heals your cold sore faster.

Who can use ABREVA?

Adults and children 12 years and over can use ABREVA.

How often can I apply ABREVA?

ABREVA 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 ABREVA?

Yes, cosmetics such as lipstick may be applied over ABREVA. 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 ABREVA.

For More Information:

Call us at 1-877-709-3539

Abreva
DOCOSANOL 10% CREAM
COLD SORE/FEVER BLISTER TREATMENT

Principal Display Panel

NDC 0135-0200-01

abreva

DOCOSANOL 10% CREAM

gsk

Cold Sore/Fever Blister Treatment

Cold Sore Treatment

Beauty Unaltered

NET WT

2g (0.07 oz)

1000771



ABREVA

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0200
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: 274KW0O50M)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0200-01	2 g in 1 TUBE; Type 0: Not a Combination Product	03/19/2010	
2	NDC:0135-0200-03	2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/19/2010	
3	NDC:0135-0200-04	2 in 1 PACKAGE	03/19/2010	02/29/2020
3		2 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0200-05	2 in 1 PACKAGE	07/06/2017	
4		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	
NDA	NDA020941	03/19/2010		

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 10/2020

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