ABREVA- docosanol cream
Haleon US Holdings 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 º-25 ºC (68 º-77 ºF)
- 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

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

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

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

Thank you for puchasing 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.

ABREVA is different from other over-the-counter cold sore products. Only ABREVA 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 ABREVA different from the Over-The-Counter cold sore remedies I have already been using?

Abreva is a non-prescription cold sore medicine that can actually shorten healing time and the duration of symptoms. The sooner you start using ABREVA, the sooner you can begin healing your cold sore.

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.

Principal Display Panel

abreva

DOCOSANOL 10% CREAM

Cold Sore/Fever Blister Treatment

Non-prescription medicine to shorten healing time*

Cold sore treatment

For topical use only

NET WT

2g (0.07 oz)

PA1001738

ABREVA

docosanol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0300
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0300-01	1 in 1 PACKAGE	03/25/2022	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0300-02	2 in 1 PACKAGE	04/25/2022	
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	ANDA208754	03/25/2022	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 6/2024

Haleon US Holdings LLC