## DOCOSANOL- docosanol cream AAFES/Your Military Exchanges

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**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 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 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 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 active ingredient in Abreva®

Docosanol Cream, 10%

Cold sore/fever blister treatment

- Only FDA approved medicine to shorten healing time.\*
- Cold sore treatment

NET WT 2g (0.07 OZ)

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

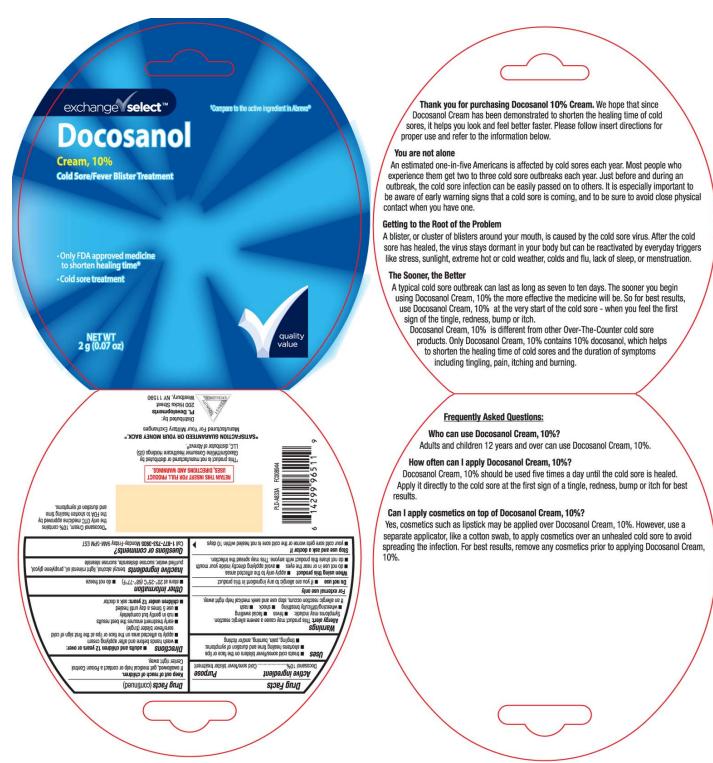
†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

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

Manufactured for Your Military Exchanges

Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590

### Package label



## **DOCOSANOL**

docosanol cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55301-112

**Route of Administration** TOPICAL

## **Active Ingredient/Active Moiety**

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	Ingredient Name	<b>Basis of Strength</b>	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: 274KW0O50M)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55301-112- 07	1 in 1 PACKAGE	12/31/2023			
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	ANDA212385	12/31/2023			