

DOCOSANOL- docosanol cream
Cardinal Health (Leader) 70000

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 ABREVA® active ingredient†

Docosanol

Cream, 10% | Cold Sore / Fever Blister Treatment

Non-Prescription

Medicine to Shorten

Healing Time*

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

LEADER Cold Sore Fever Blister Treatment

DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0517
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: 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:70000-0517-1	1 in 1 PACKAGE	09/17/2019	
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	09/17/2019	

Revised: 10/2023

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