

DOCOSANOL- docosanol cream
Care One (Retail Business Services, LLC.)

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 TREATMENT

Non-prescription

medicine to shorten healing time.*

For topical use only

NET WT 2g (0.07 OZ)

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTION AND WARNINGS.

DISTRIBUTED BY:

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-922
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: 059QF0KO0R)	
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:72476-922-07	1 in 1 PACKAGE	06/30/2020	
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	06/30/2020	

Labeler - Care One (Retail Business Services, LLC.) (967989935)