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/FEVER BLISTER TREATMENT

Non-prescription medicine to shorten healing time*

Cold sore treatment

For topical use only

NET WT 2g (0.07 OZ)

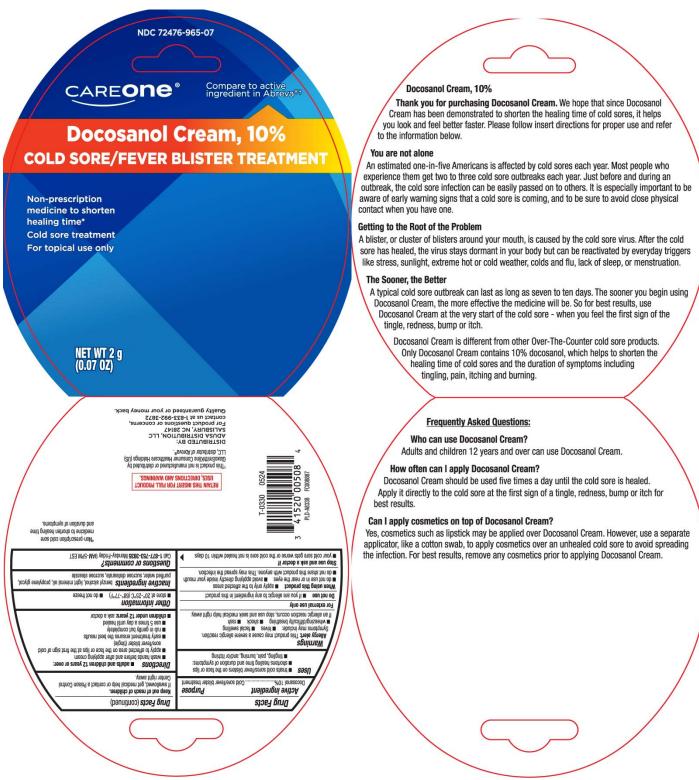
*Non-prescription cold sore medicine to shorten healing time and duration of symptoms.

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

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

DISTRIBUTED BY:
ADUSA DISTRIBUTION, LLC
SALISBURY, NC 28147

Package label



DOCOSANOL

docosanol cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-965

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: 274KW0O50M)		

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

. ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-965- 07	1 in 1 PACKAGE	12/31/2023	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212385	12/31/2023	

Care One (Retail Business Services, LLC.)

Revised: 5/2024