COLD SORE FEVER BLISTER TREATMENT- docosanol cream Topco Associates

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 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 toll free 1-888-423-0139

Principal Display Panel

†COMPARE TO THE ACTIVE INGREDIENT IN ABREVA®

Cold Sore Treatment

COLD SORE/FEVER BLISTER TREATMENT

DOCOSANOL CREAM, 10%

- Only FDA Approved Medicine to Shorten Healing Time*
- Cold Sore Treatment

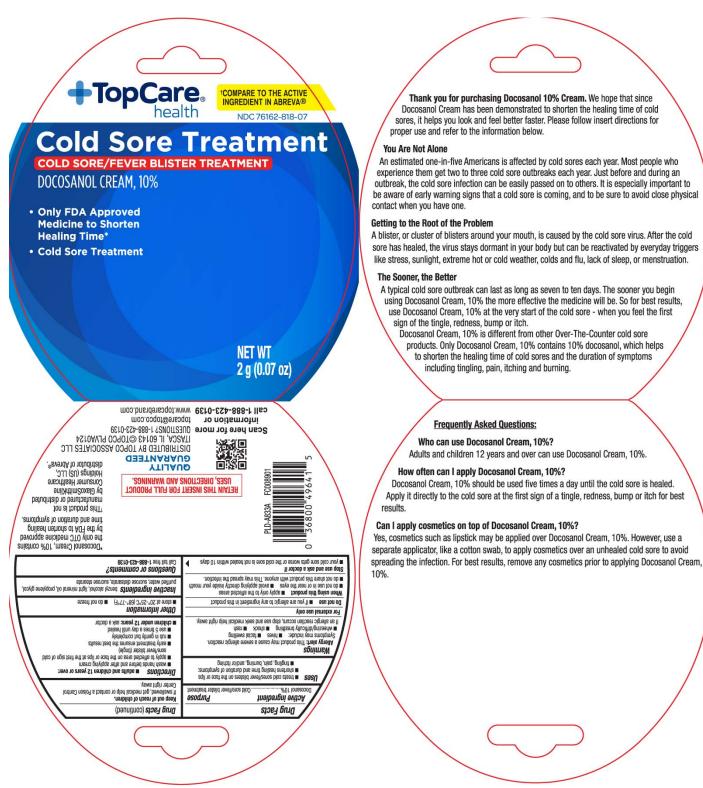
NET WT 2 g (0.07 oz)

*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

Package Label



COLD SORE FEVER BLISTER TREATMENT

docosanol cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-818

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

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-818- 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			

Revised: 4/2024 Topco Associates