

COLD SORE TREATMENT DOCOSANOL- docosanol cream

Blistex Inc.

Cold Sore Treatment: Docosanol Cream 10%

Drug Facts

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 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 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 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 and sucrose stearate

Questions or comments?

www.blistex.com

Distributed by: Blistex Inc.,
P.O. Box 5392, Oak Brook, IL 60522-5392

PRINCIPAL DISPLAY PANEL - 2 g Tube Blister Pack

NDC 10157-2124-2

Blistex®

DERMATOLOGIST RECOMMENDED

NEW

COLD SORE
TREATMENT

Docosanol Cream 10%
COLD SORE / FEVER BLISTER TREATMENT

+

FDA APPROVED MEDICINE
to Shorten Healing Time*

For Topical Use Only
NET WT. 2 g (0.07 oz)
#C010319

NDC 10157-2124-2

Blistex[®]

DERMATOLOGIST RECOMMENDED

**COLD SORE
TREATMENT**

Docosanol Cream 10%
COLD SORE / FEVER BLISTER TREATMENT

FDA APPROVED MEDICINE
to Shorten Healing Time*

Cut out for
blister (stripped)

For Topical Use Only

NET WT. 2 g (0.07 oz)

#C010319

NEW



Blistex[®]

DERMATOLOGIST RECOMMENDED

COLD SORE TREATMENT

Docosanol Cream 10%

*Docosanol Cream contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient Purpose Docosanol 10%.....Cold sore/ fever blister treatment	For external use only Do not use • If you are allergic to any ingredient in this product	• wash hands before and after applying cream • apply to affected area on 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
Uses • treats cold sores/fever blisters on the face or lips • shortens healing time and duration of symptoms: • tingling, pain, burning, and/or itching	When using this product • apply only to 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 infection.	Other information • store at 20° to 25°C (68° to 77°F). • do not freeze
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. ▶	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.	Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate
	Directions • adults and children 12 years or over: ▶	Questions or comments? www.blistex.com

Retain this insert for full product uses, directions and warnings.



Distributed by: Blistex Inc.,
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Code: TS/DRUGS/58039/2020
Made in India
#C010320
P4100434

COLD SORE TREATMENT DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-2124
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: 059QF0KO0R)	
SUCROSE DISTEARATE (UNII: 33X4X4B90S)	

SUCROSE STEARATE (UNII: 274KW0050M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-2124-2	1 in 1 BLISTER PACK	05/01/2025	
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		ANDA217090	05/01/2025	

Labeler - Blistex Inc. (005126354)

Establishment			
Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-2124)

Revised: 4/2025

Blistex Inc.