

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.

<p>Drug Facts</p> <p>Active ingredient Purpose Docosanol 10%.....Cold sore/fever blister treatment</p>	<p>Drug Facts (continued)</p> <p>For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> If you are allergic to any ingredient in this product 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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
<p>Uses</p> <ul style="list-style-type: none"> treats cold sores/fever blisters on the face or lips shortens healing time and duration of symptoms: <ul style="list-style-type: none"> tingling, pain, burning, and/or itching 	<p>When using this product</p> <ul style="list-style-type: none"> 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. 	<p>Other information</p> <ul style="list-style-type: none"> store at 20° to 25°C (68° to 77°F). do not freeze
<p>Warnings</p> <p>Allergy alert This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> hives facial swelling wheezing/difficulty breathing shock rash <p>If an allergic reaction occurs, stop use and seek medical help right away. ▶</p>	<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> your cold sore gets worse or the cold sore is not healed within 10 days. <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years or over: ▶ 	<p>Inactive ingredients</p> <p>benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate</p> <p>Questions or comments? www.blistex.com</p>

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: 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)

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.