

DOCOSANOL- docosanol cream
Sun Pharmaceutical Industries, Inc.

Docosanol

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 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 between 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?

call **1-866-923-4914**

TAMPER-EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 2 g Tube Package

NDC 51672-1406-3

Compare to the active ingredient in Abreva[®]*

Docosanol
Cream 10%

Cold Sore
Fever Blister
Treatment

Cold Sore
Treatment

Only FDA

Approved
 Medicine to
 Shorten
 Healing Time †

For Topical Use Only

Net Wt. 2 g (0.07 oz)

Dist. by: Taro Pharmaceuticals U.S.A., Inc.
 Hawthorne, NY 10532 Made in Canada

Docosanol Cream 10%

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

[†]Contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.

Drug Facts		Drug Facts (continued)	
Active ingredient	Purpose	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Docosanol 10%...Cold sore/fever blister treatment			
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Stop use and ask a doctor if		TAMPER-EVIDENT; DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE	
<ul style="list-style-type: none"> your cold sore gets worse or the cold sore is not healed within 10 days 			

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 764378
 51672-14063 2
 3

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Abreva®

Docosanol Cream 10%

Cold Sore Fever Blister Treatment

Cold Sore Treatment

Only FDA Approved Medicine to Shorten Healing Time†

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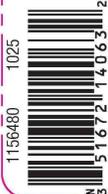
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ohm
LABORATORIES INC.
a SUN PHARMA company

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NDC 51672-1406-3

Docosanol Cream 10%

Cold Sore
Fever Blister
Treatment

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Only FDA
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Medicine to
Shorten
Healing Time†



For Topical Use Only

Net Wt. 2 g (0.07 oz)

Distributed by: Ohm Laboratories Inc.
New Brunswick, NJ 08901 Made in Canada

DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-1406
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 STEARATE (UNII: 274KW0050M)	
SUCROSE DISTEARATE (UNII: 33X4X4B90S)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-1406-3	1 in 1 PACKAGE	10/26/2023	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-1406-2	2 in 1 PACKAGE	10/26/2023	
2		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	ANDA214454	10/26/2023	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment			
Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-1406)