

DOCOSANOL - docosanol cream
Aleor Dermaceuticals Limited

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 ingredient

benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate, sucrose stearate

Questions or comments?

Call **1-866-210-9797** Monday-Friday 9AM-6PM EST

PRINCIPAL DISPLAY PANEL

Tube pack

NDC 71589-019-01

Docosanol Cream, 10%

Compare to the active ingredient in Abreva®**

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)

**This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

*Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

Manufactured for:

Aleor Dermaceuticals Ltd.,
 Karakhadi, Vadodara 391450, India.

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

Compare to the active ingredient in Abreva®**

NDC 71589-019-01

Drug Facts

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Drug Facts (continued)

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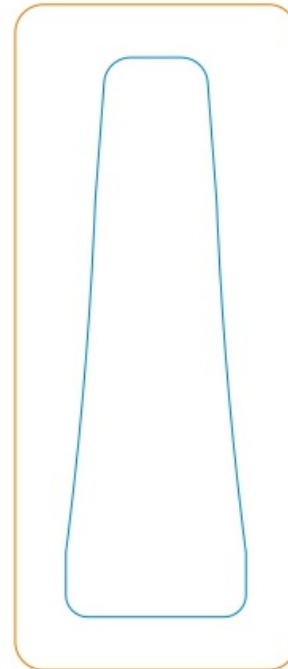
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Manufactured for: **Aleor Dermaceuticals Ltd.,**
 Karakhadi, Vadodara 391450, India.

Made in India.
 Mfg. License No.: G/25/2216



UVZ
 30 x 11mm

5/2022
 XXXXXXXX

Sap Code

Batch Coding
 (For Reference Only)
 LOT: 1234567890
 EXP: MMM YYYY

PUMP PACK

NDC 71589-019-03

Docosanol Cream, 10%

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Manufactured for:

Aleor Dermaceuticals Ltd.,

Karakhadi, Vadodara 391450, India.

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Press Pump completely about 6 to 8 times to get first dose.



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 Karakhadi, Vadodara 391450, India.
 Made in India. Mfg. License No.: G/25/2216



UVZ
30 x 16mm

Sap Code

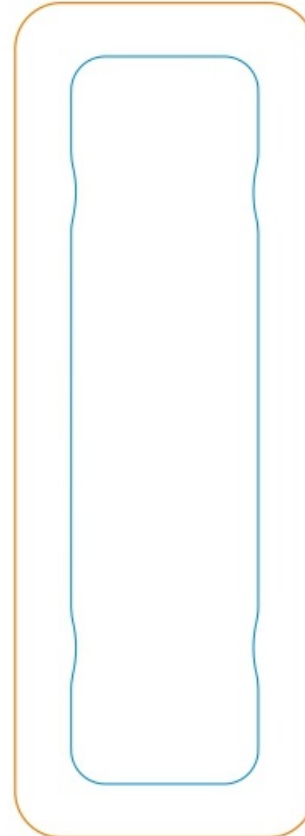
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NDC 71589-019-03

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Cold Sore/Fever Blister Treatment
 Non-prescription Medicine to Shorten Healing Time*



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- For Topical Use Only

Portable Convenient Pump



NET WT
2 g
(0.07 oz)



DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71589-019
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)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71589-019-01	1 in 1 PACKAGE	05/03/2022	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71589-019-03	1 in 1 PACKAGE	05/03/2022	
2		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA215839	05/03/2022		

Labeler - Aleor Dermaceuticals Limited (871411532)

Registrant - Aleor Dermaceuticals Limited (871411532)

Establishment

Name	Address	ID/FEI	Business Operations
Aleor Dermaceuticals Limited		871411532	MANUFACTURE(71589-019) , ANALYSIS(71589-019)