DOCOSANOL - docosanol cream Aurohealth LLC

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?

call toll-free 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

Additional information

*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.

Distributed by:

AUROHEALTH LLC,

279 Princeton-Hightstown Road,

East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/58039/2020

Thank you for purchasing Docosanol Cream. We hope that since docosanol cream shortens the healing time of cold sores, it helps you look and feel better faster. Please follow insert directions for proper use and refer to the information below.

You are not alone

An estimated one-in-five Americans is affected by cold sores each year. Most people who experience them get two to three cold sore outbreaks each year. Just before and during an outbreak, the cold sore infection can be easily passed on to others. It is especially important to be aware of early warning signs that a cold sore is coming, and to be sure to avoid close physical contact when you have one.

Getting to the Root of the Problem

A blister, or cluster of blisters around your mouth, is caused by the cold sore virus. After the cold sore has healed, the virus stays dormant in your body but can be reactivated by everyday triggers like stress, sunlight, extreme hot or cold weather, colds and flu, lack of sleep, or menstruation.

The Sooner, the Better

A typical cold sore outbreak can last as long as seven to ten days. The sooner you begin using docosanol cream, the more effective the medicine will be. So for best results, use docosanol cream at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.

Docosanol cream is different from other over-the-counter cold sore products. Only docosanol cream contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including tingling, pain, itching and burning.

Frequently Asked Questions:

How is docosanol cream different from the over-the-counter cold sore remedies I have already been using?

Docosanol cream is the only FDA approved non-prescription cold sore medicine that can actually shorten healing time and the duration of symptoms. The sooner you start using docosanol cream, the sooner you can begin healing your cold sore.

Who can use docosanol cream?

Adults and children 12 years and over can use docosanol cream.

How often can I apply docosanol cream?

Docosanol cream should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best

results.

Can I apply cosmetics on top of docosanol cream?

Yes, cosmetics such as lipstick may be applied over docosanol cream. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying docosanol cream.

How to use your docosanol cream Pump (for pump pack)

- For Adults and Children 12 years and older

- Docosanol cream should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.

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STEP 1 - Wash your hands before and after treating the cold sore.

STEP 2 – Remove cap and press pump firmly. When first used, expect to press pump completely about 6 to 8 times before obtaining first dose.

STEP 3 – Rub in gently but completely 5 times a day until healed for maximum of 10 days.

STEP 4 - Place cap back on pump after each use.

For more information:

Call us at 1-855-274-4122

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Label 10% (2 g Tube)

AUROHEALTH NDC 58602-019-07 Docosanol Cream 10% Cold Sore/Fever Blister Treatment For Topical Use Only NET WT 2 g (0.07 oz)

AUROHEALTH Docosanol Cream Cold Sore/Fever Blister Treat For Topical Use Only		
Retain insert for full product uses, directions and warnings.		
Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road, East Windsor, NJ 08520		
Made in India Code: TS/DRUGS/58039/2020	P4200007	

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Square Blister Card Label 10% (2 g Tube)

AUROHEALTH

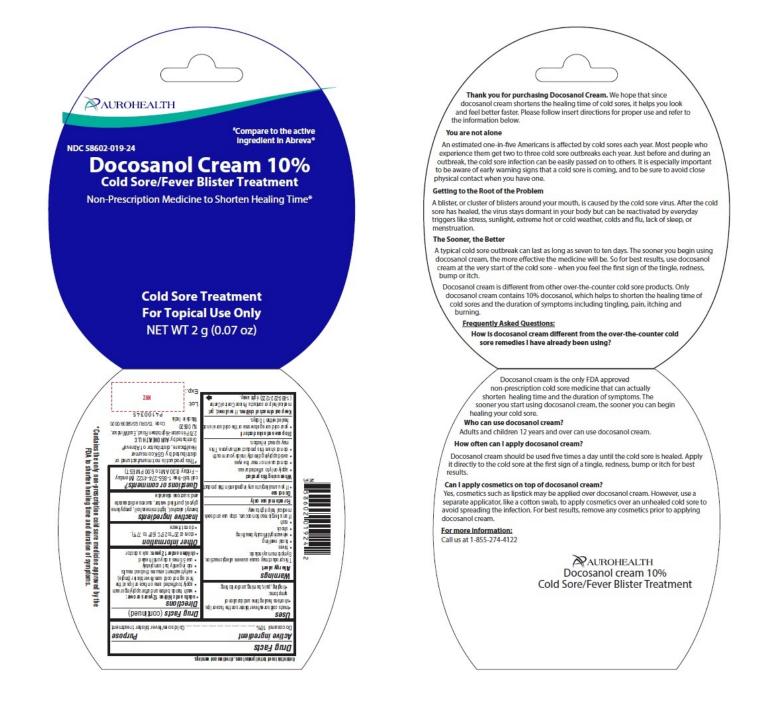
#Compare to the active ingredient in Abreva[®]
NDC 58602-019-08
Docosanol Cream 10%
Cold Sore/Fever Blister Treatment
Non-Prescription Medicine to Shorten Healing Time*
Cold Sore Treatment
For Topical Use Only
NET WT 2 g (0.07 oz)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Tube Clamshell Blister Card label 10% (2 g Tube)

AUROHEALTH

#Compare to the active Ingredient in Abreva[®]
NDC 58602-019-24
Docosanol Cream 10%
Cold Sore/Fever Blister Treatment
Non-Prescription Medicine to Shorten Healing Time*
Cold Sore Treatment
For Topical Use Only
NET WT 2 g (0.07 oz)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Pump Label 10% (2 g Pump)

AUROHEALTH NDC 58602-019-14 Docosanol Cream 10% Cold Sore/ Fever Blister Treatment For Topical Use Only NET WT 2 g (0.07 oz)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Pump Square Blister Card Label 10% (2 g Pump)

AUROHEALTH

#Compare to the active ingredient in Abreva[®] NDC 58602-019-15 **Docosanol Cream 10% Cold Sore/Fever Blister Treatment** Non-Prescription Medicine to Shorten Healing Time* Portable Convenient Pump **Cold Sore Treatment**

For Topical Use Only

NET WT 2 g (0.07 oz)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Pump Clamshell Blister Card Label 10% (2 g Pump)

AUROHEALTH

#Compare to the active Ingredient in Abreva[®]
NDC 58602-019-16
Docosanol Cream 10%
Cold Sore/Fever Blister Treatment

Non-Prescription Medicine to Shorten Healing Time* Portable

Convenient Pump Cold Sore Treatment For Topical Use Only **Read Inside fold out** for full details NET WT

2 g (0.07 oz)



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How to use your docosanol cream Pump

How to use your docosanol cream Pump - for Adults and Children 12 years and older - Docosanol cream should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results. - If you wish, you can apply cosmetics such as lipstick over docosanol cream. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying docosanol cream.



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For more information: Call us at 1-855-274-4122

AUROHEALTH Docosanol Cream 10% Cold Sore/Fever Blister Treatment

DOCOSANOL

docosanol cream

	roduct Info	rmation						
			HUMAN OTC DRUG	IMAN OTC DRUG Item Code (Source)			NDC:58602-019	
			TOPICAL		• • • •	(000100)		
Ac	tive Ingred	ient/Active	Moiety					
		Ingred	ient Name		Basis of Strengt			Strength
DOCOSANOL (UNII: 9G10E216XY) (DOCOSANOL - UNII:9G10E216XY) DOCOSANO						DOCOSANOL		100 mg in 1 g
In	active Ingre	edients						
Ingredient Name							9	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)								
LIGHT MINERAL OIL (UNII: N6K5787QVP)								
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)								
WATER (UNII: 059QF0KO0R) SUCROSE DISTEARATE (UNII: 33X4X4B90S)								
		ATE (UNII: 274KV						
Pr	oduct Char	acteristics						
Co	lor		WHITE Score					
	аре			Size				
Flavor								
	_			Imprint Co	de			
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				Imprint Co	de			
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		Pa	ckage Descriptio			arketing Start Date	Ma	rketing End Date
Pa #	ickaging	Pa 1 in 1 PACKAGE			Ma		Ма	
Pa # 1	Item Code	1 in 1 PACKAGE		'n	Ma	Date	Ma	
Pa # 1	Item Code NDC:58602- 019-08	1 in 1 PACKAGE	Type 0: Not a Combina	'n	Ma 03/0	Date	Ma	
Pa # 1	Item Code NDC:58602- 019-08	1 in 1 PACKAGE 2 g in 1 TUBE; 1 in 1 PACKAGE	Type 0: Not a Combina	n ation Product	Ma 03/0	Date 1/2024	Ma	
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M	larketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Ν	larketing	Information		
9		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
9	NDC:58602- 019-17	2 in 1 PACKAGE	03/01/2024	
8		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
8	NDC:58602- 019-16	1 in 1 PACKAGE	03/01/2024	
		Product		

Labeler - Aurohealth LLC (078728447)

Establishment					
Name	Address	ID/FEI	Business Operations		
APL HEALTHCARE LIMITED		878100017	ANALYSIS(58602-019), MANUFACTURE(58602-019)		

Revised: 3/2024

Aurohealth LLC