DOCOSANOL- docosanol cream H2-Pharma, LLC

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 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 (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 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°-25°C (68°-77°F)
- do not freeze

Inactive ingredients

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

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**

Montgomery, AL 36117

PRINCIPAL DISPLAY PANEL - 2 g Bottle Package

NDC 61269-989-37 †Compare to the active ingredient in Abreva®

Docosanol Cream 10% Cold sore/fever blister treatment

Portable convenient pump

Only FDA-approved medicine to shorten healing time*

Cold sore treatment

Net wt. 2 g (0.07 oz)

Docosanol Cream 10%

Cold sore/fever blister treatment

NDC 61269-989-37 †Compare to the active ingredient in Abreva®

Portable convenient pump



Only FDA-approved medicine to shorten healing time*
Cold sore treatment

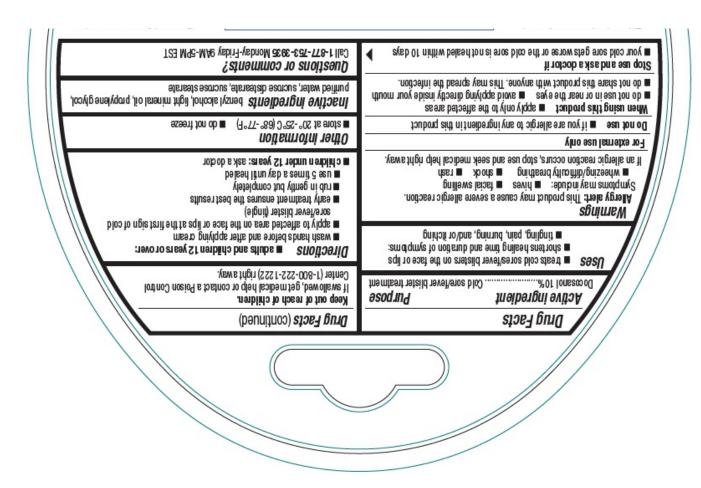
Net wt. 2 g (0.07 oz)

H²pharma

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS. Distributed by: H2-Pharma, LLC Montgomery, AL 36117 www.h2-pharma.com

*Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms. **NO COATING**

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



DOCOSANOL

docosanol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61269-989
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: 274KW0O50M)				

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:61269- 989-37	1 in 1 PACKAGE	07/18/2023	
l	1	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	ANDA212385	07/18/2023	

Labeler - H2-Pharma, LLC (028473634)

Revised: 7/2023 H2-Pharma, LLC