

**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 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 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 Tube Package**

NDC 61269-981-35

†Compare to the active ingredient in Abreva®

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)

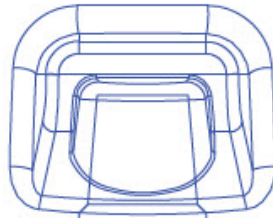
H<sup>2</sup> pharma

NDC 61269-981-35  
†Compare to the active ingredient in Abreva®

# Docosanol Cream 10%

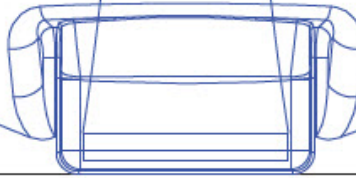
Cold sore/fever blister treatment

Non-prescription medicine to shorten healing time\*  
Cold sore treatment  
For topical use only



FPO

Net wt. 2 g  
(0.07 oz)



RD-A611A F007475

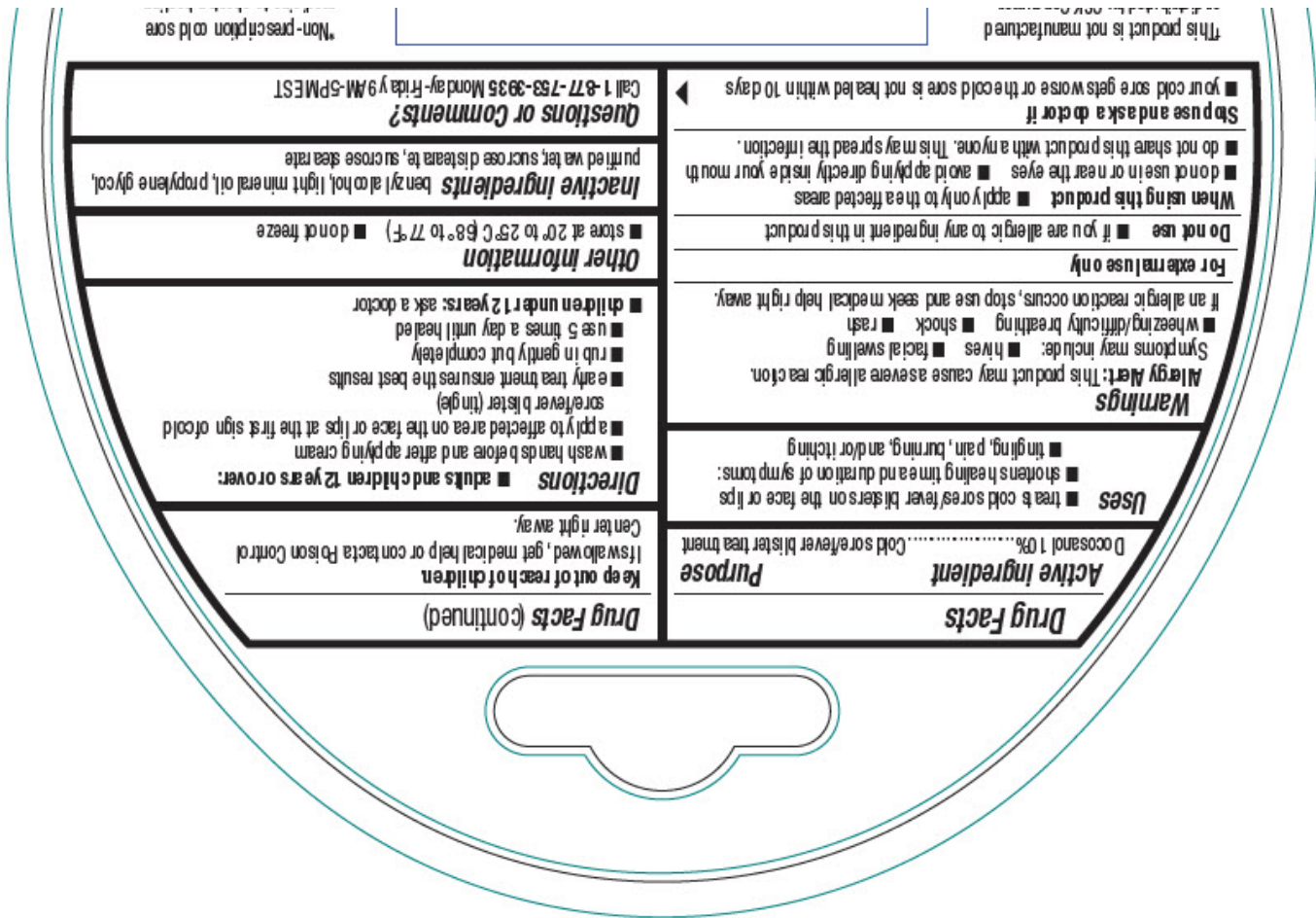
Distributed by: H2-Pharma, LLC  
Montgomery, AL 36117  
www.h2-pharma.com

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS.

NO COATING

medicine to shorten healing time and duration of symptoms

or distributed by usk consumer healthcare, distributor of Abreva®



# DOCOSANOL

docosanol cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:61269-981 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>DOCOSANOL</b> (UNII: 9G1OE216XY) (DOCOSANOL - UNII:9G1OE216XY) | DOCOSANOL         | 100 mg in 1 g |

## Inactive Ingredients

| Ingredient Name                              | Strength |
|--|----------|
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)     |          |
| <b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)  |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)   |          |
| <b>WATER</b> (UNII: 059QF0KO0R)              |          |
| <b>SUCROSE DISTEARATE</b> (UNII: 33X4X4B90S) |          |
| <b>SUCROSE STEARATE</b> (UNII: 274KW0050M)   |          |

## Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | WHITE | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:61269-981-35 | 1 in 1 PACKAGE                                   | 06/29/2021           |                    |
| 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               | ANDA208754                               | 06/29/2021           |                    |

**Labeler -** H2-Pharma, LLC (028473634)

Revised: 1/2023

H2-Pharma, LLC