

DOCOSANOL- docosanol cream
United Natural Foods, Inc. dba UNFI

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 ingredients

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

Questions or Comments?

Call **toll free 1-855-423-2630**

Principal display panel

Compare to active ingredient in Abreva®†

Docosanol Cream 10%

Cold sore/fever blister treatment

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

For topical use only

NET WT 2g (0.07 OZ)

*Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

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

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83455-112 |
| 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: 059QF0KOOR) | |
| 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:83455-112-07 | 1 in 1 PACKAGE | 12/31/2023 | |
| 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 | ANDA212385 | 12/31/2023 | |

Labeler - United Natural Foods, Inc. dba UNFI (943556183)