

**DOCOSANOL- docosanol cream**  
**Rugby Laboratories**

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

**PRINCIPAL DISPLAY PANEL**

**TUBE PACK**

**NDC 0536-1427-04**

**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

**Distributed by:**

**RUGBY® LABORATORIES**

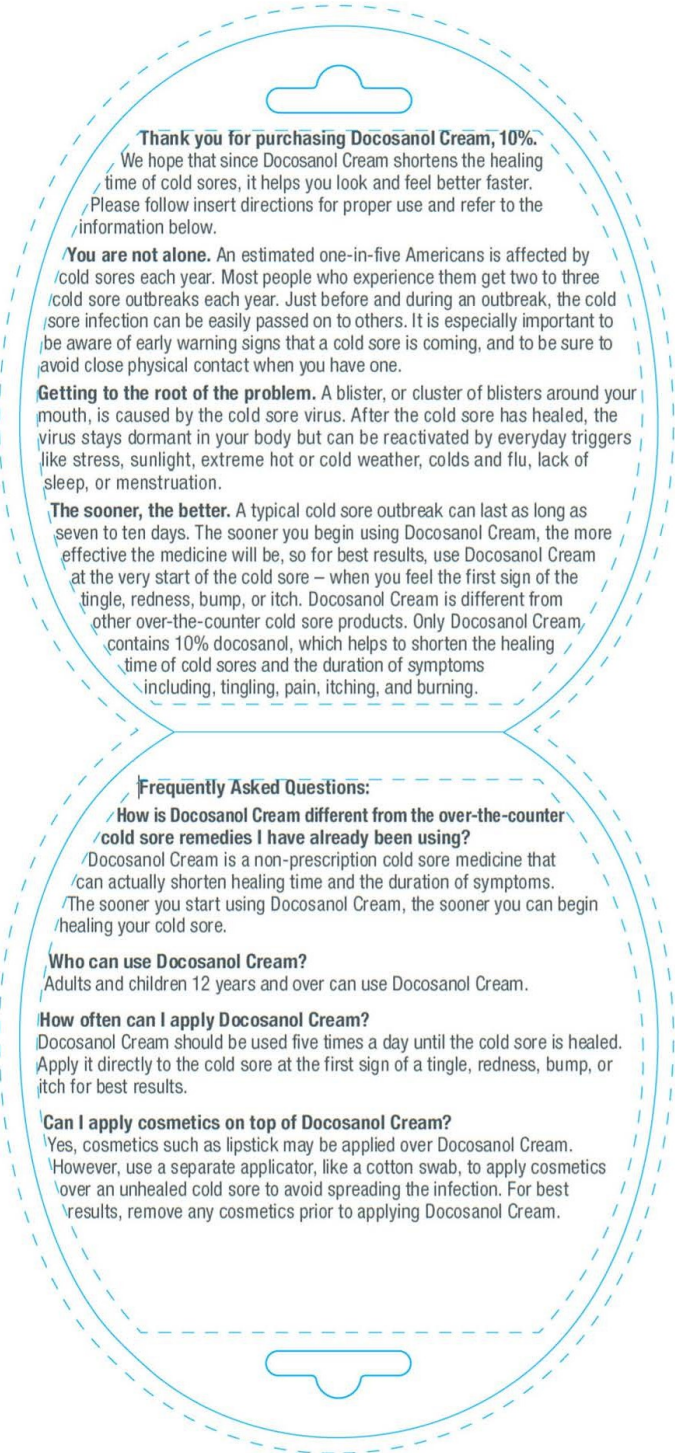
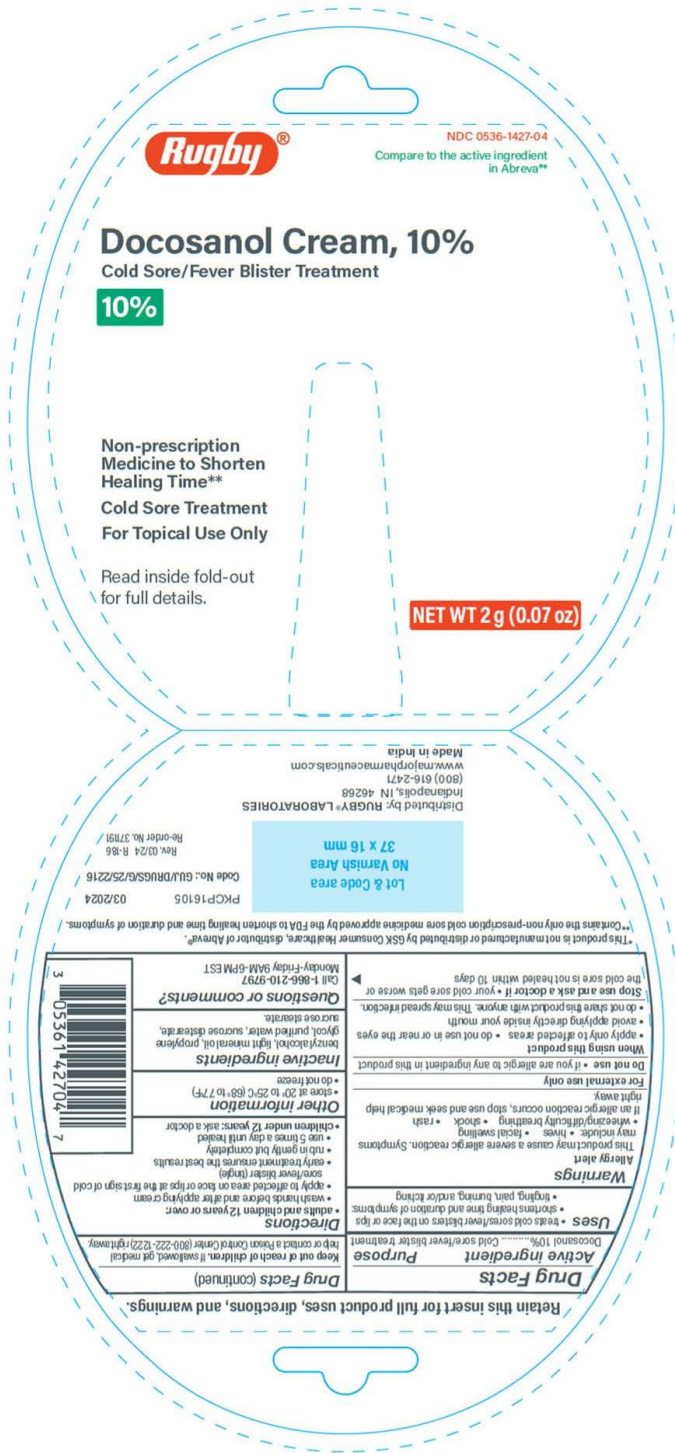
Indianapolis, IN 46268

(800) 616-2471

[www.majorpharmaceuticals.com](http://www.majorpharmaceuticals.com)

Code No.: GUJ/DRUGS/G/25/2216

Made in India



# DOCOSANOL

docosanol cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1427
<b>Route of Administration</b>	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: 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:0536-1427-04	1 in 1 PACKAGE	05/22/2024	
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	ANDA215839	05/22/2024		

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Alembic Pharmaceuticals Limited (650574663)

### Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(0536-1427) , ANALYSIS(0536-1427)

### Establishment

Name	Address	ID/FEI	Business Operations
Contract Packaging Resources, Inc.		960203917	PACK(0536-1427)

