

JULIE COLD SORE TREATMENT- docosanol cream
Julie Products Inc

Pull tab to soothe your cold sore

Drug Facts

Active ingredient	Purpose
Docosanol 10%.....	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
*800-222-1222) right away.

Drug Facts (continued)

Directions

- **adults and children 12 years or over:** cream
- wash hands before and after applying
- 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 1-855-274-4142 (Monday – Friday 8:30 AM to 5:00 PM EST)

#This product is not manufactured or distributed by GSK consumer Healthcare, distributor of Abreva®

Julie™

Distributed by:
JULIE PRODUCTS, INC.
1001 W Bluff Rd,
Romeoville, IL 60446

Made in India
Code: TS/DRUGS/58039/2020

Retain this insert for full product uses, directions and warnings

*Contains only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms

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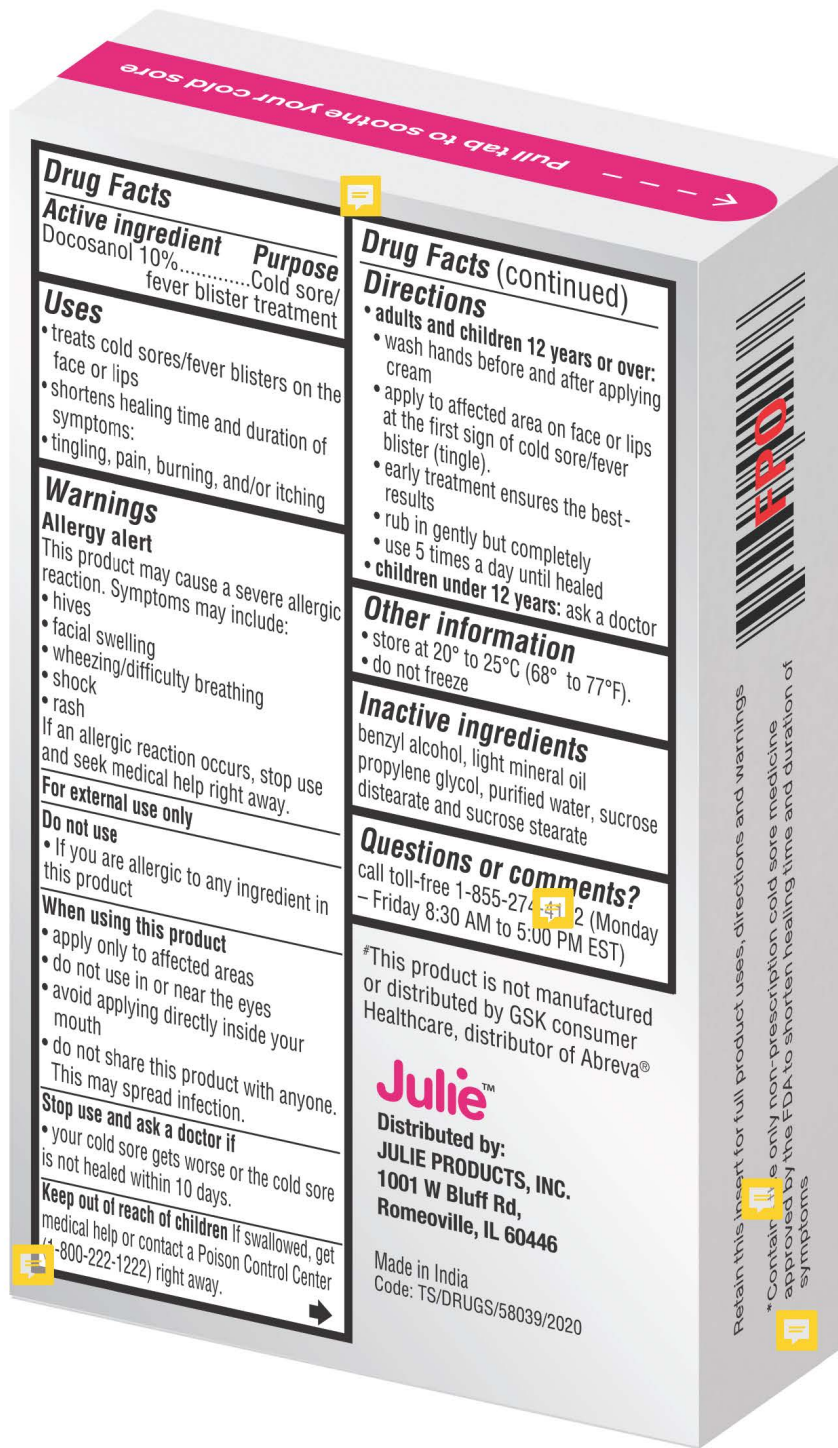
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docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82791-362
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCOSANOL (UNII: 9G1OE216XY) (DOCOSANOL - UNII:9G1OE216XY)	DOCOSANOL	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
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:82791-362-01	2 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217090	04/01/2024	

Labeler - Julie Products Inc (118628472)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		878100017	manufacture(82791-362) , analysis(82791-362)

