

JULIE COLD SORE TREATMENT- docosanol cream
Julie Products Inc



Retain this insert for full product uses, directions and warnings
 *Contains Docosanol 10%, the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms
 NDC 82791-362-01

Female Founded

Julie™

DOCOSANOL
10% CREAM

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)



Find out more about Julie For All

*Compare to the active Ingredient In Abreva®

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<p>Drug Facts</p> <p>Active ingredient Purpose Docosanol 10%.....Cold sore/ fever blister treatment</p> <p>Uses • treats cold sores/fever blisters on the face or lips • shortens healing time and duration of symptoms: • tingling, pain, burning, and/or itching</p> <p>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.</p> <p>For external use only</p> <p>Do not use • If you are allergic to any ingredient in this product</p> <p>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.</p> <p>Stop use and ask a doctor if • your cold sore gets worse or the cold sore is not healed within 10 days.</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. ➔</p>	<p>Drug Facts (continued)</p> <p>Directions • adults and children 12 years or over: • wash hands before and after applying cream • 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</p> <p>Other information • store at 20° to 25°C (68° to 77°F). • do not freeze</p> <p>Inactive ingredients benzyl alcohol, light mineral oil propylene glycol, purified water, sucrose distearate and sucrose stearate</p> <p>Questions or comments? call toll-free 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)</p> <p>*This product is not manufactured or distributed by GSK consumer Healthcare, distributor of Abreva®</p> <p style="text-align: center;">Julie™</p> <p>Distributed by: JULIE PRODUCTS, INC. 1001 W Bluff Rd, Romeoville, IL 60446</p> <p style="font-size: 8px;">Made in India Code: TS/DRUGS/58039/2020</p>
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Drug Facts (continued)

Directions

- adults and children 12 years or over:
- wash hands before and after applying cream
- 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

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

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

Uses
• treats cold sores/fever blisters on the
face or lips
• shortens healing time and duration of
symptoms:
• tingling, pain, burning, and/or itching

Keep out of reach of children if swallowed, get
medical help or contact a Poison Control Center
(1-800-222-1222) right away. ➔

Drug Facts

Active ingredient	Purpose
Docosanol 10%	Cold sore/ fever blister treatment

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Docosanol 10%	Cold sore/ fever blister treatment

JULIE COLD SORE TREATMENT

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: 9G10E216XY) (DOCOSANOL - UNII:9G10E216XY)	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	07/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217090	07/02/2024	

Labeler - Julie Products Inc (118628472)

Establishment

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

Revised: 7/2024

Julie Products Inc