

**DOCOSANOL- docosanol cream**  
**Taro Pharmaceuticals U.S.A., Inc.**

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**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 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 right away.

### **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

### **Other information**

- store between 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 **1-866-923-4914**

**TAMPER-EVIDENT:** DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**  
Hawthorne, NY 10532

### **PRINCIPAL DISPLAY PANEL - 2 g Tube Package**

NDC 51672-1406-3

Compare to the active ingredient in Abreva<sup>®</sup>\*

Docosanol  
Cream 10%

Cold Sore  
Fever Blister  
Treatment

Cold Sore  
Treatment

Only FDA

Approved  
 Medicine to  
 Shorten  
 Healing Time<sup>†</sup>

For Topical Use Only

Net Wt. 2 g (0.07 oz)

Dist. by: Taro Pharmaceuticals U.S.A., Inc.  
 Hawthorne, NY 10532 Made in Canada



## DOCOSANOL

docosanol cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51672-1406

**Route of Administration** 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 stearate</b> (UNII: 274KW0050M)	
<b>sucrose distearate</b> (UNII: 33X4X4B90S)	

### 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:51672-1406-3	1 in 1 PACKAGE	10/26/2023	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-1406-2	2 in 1 PACKAGE	10/26/2023	
2		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	ANDA214454	10/26/2023	

**Labeler** - Taro Pharmaceuticals U.S.A., Inc. (145186370)

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-1406)

Revised: 11/2023

Taro Pharmaceuticals U.S.A., Inc.