

**DOCOSANOL- docosanol cream**  
**Safeway, Inc.**

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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
- 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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

**Principal Display Panel**

†Compare to the active ingredient in Abreva®

Docosanol Cream, 10%

Cold sore/fever blister treatment

- Only FDA approved medicine to shorten healing time\*
- Cold Sore Treatment

NET WT 2 g (0.07 oz)

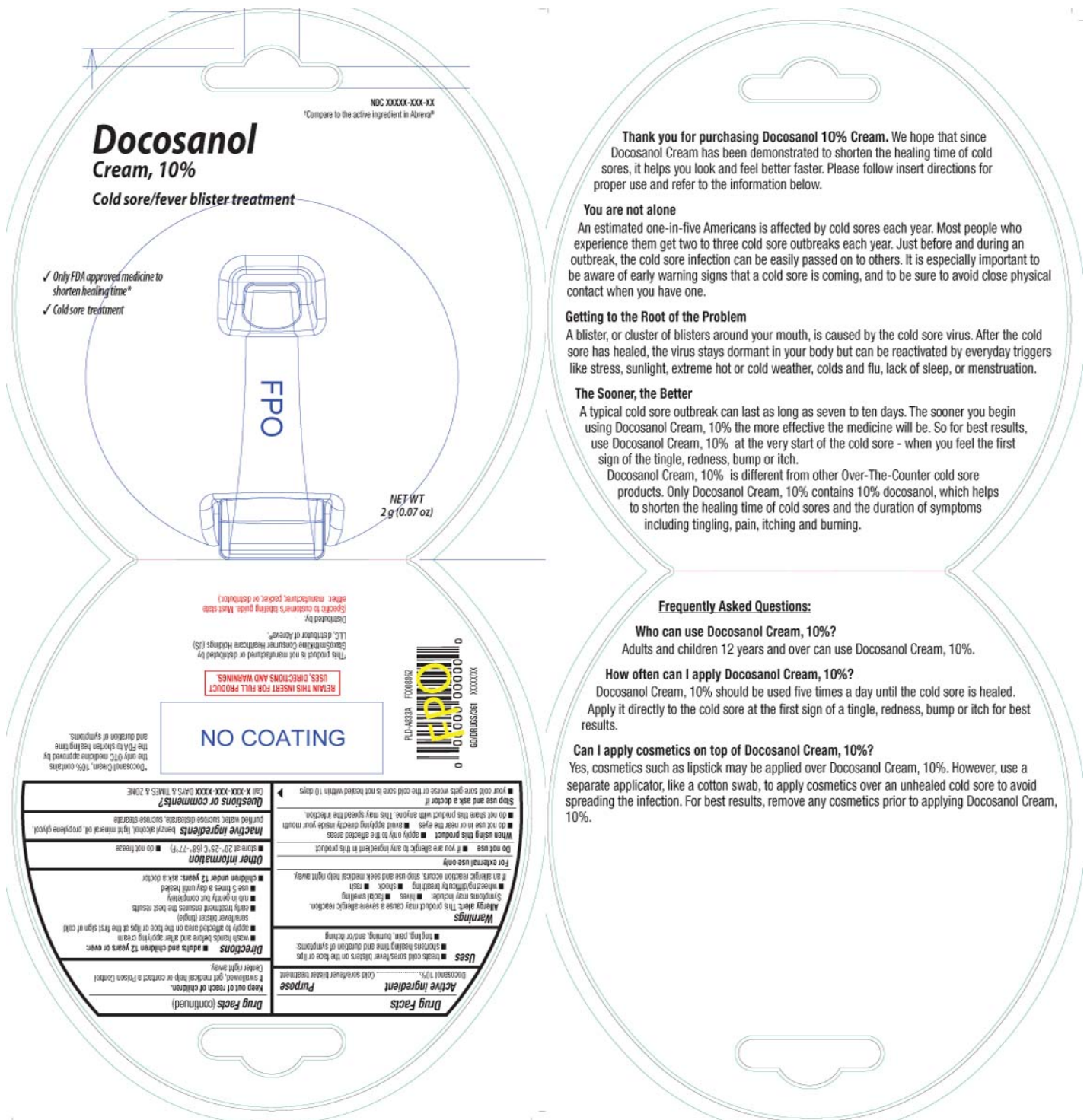
\*\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Abreva®.

\*Docosanol Cream, 10% contains the only OTC 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

## Package Label



**SIGNATURE CARE Cold Sore Fever Blister Treatment**

**DOCOSANOL**  
docosanol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-770
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCROSE DISTEARATE (UNII: 33X4X4B90S)	
SUCROSE STEARATE (UNII: 274KW0O50M)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-770-07	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** - Safeway, Inc. (009137209)