#### DOCOSANOL- docosanol cream Alembic Pharmaceuticals 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 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 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 62332-682-01

## Docosanol Cream, 10%

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

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 $^{\ensuremath{\mathbb{R}}}$ .

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

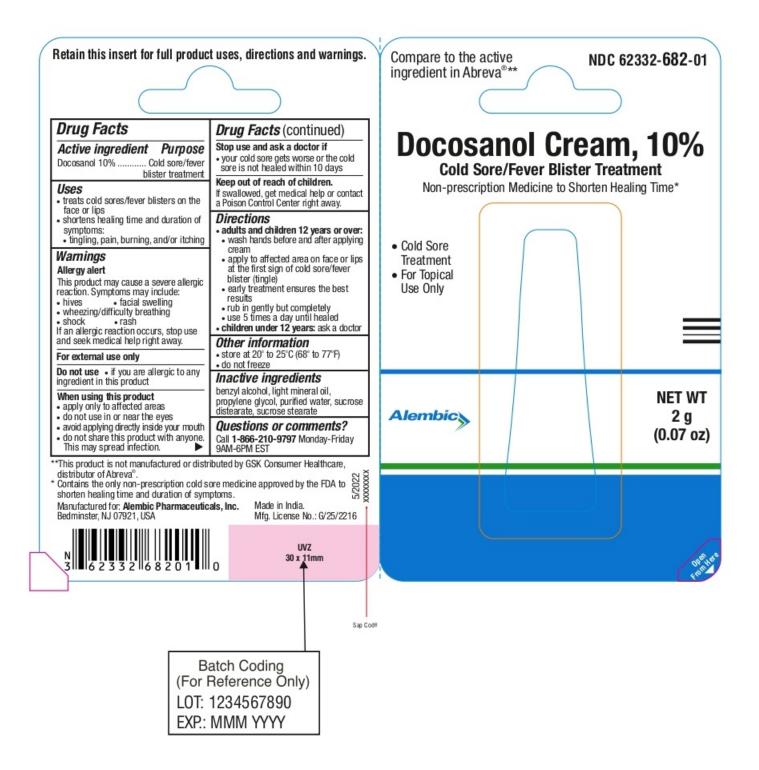
RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

Manufactured for:

# Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Made in India.



# Pump Pack

## NDC 62332-682-03

## Docosanol Cream, 10%

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

Cold Sore/Fever Blister Treatment

Non-prescription Medicine to Shorten Healing Time\*

Cold Sore Treatment

For Topical Use Only

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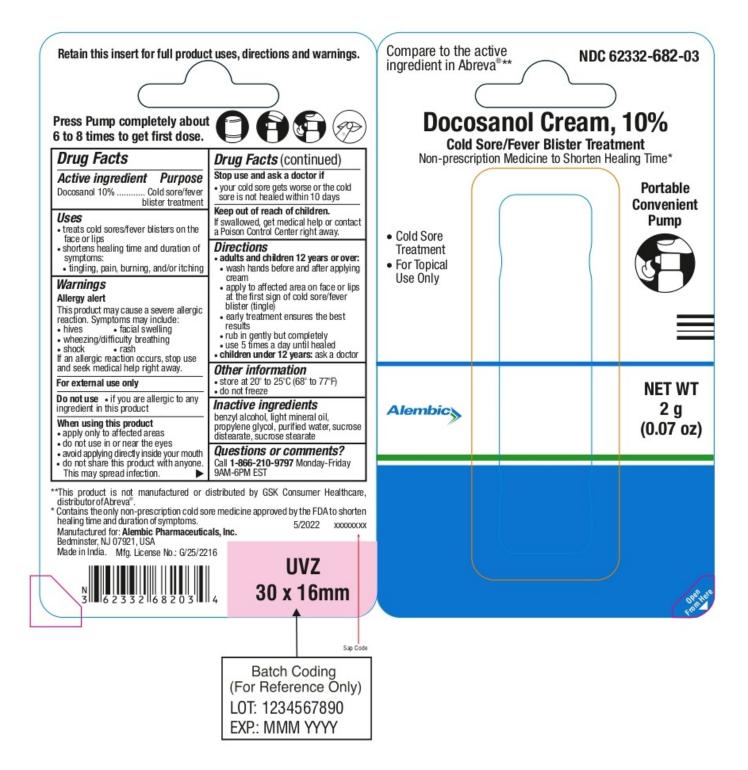
RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

Manufactured for:

## Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Made in India.



DOCOSANOL									
docosanol cream									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62332-682						
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									

		Ingred	<b>Basis of Strength</b>		Strength		
DOCOSANOL (UNII: 9G10E216XY) (DOCOSAN			DOCOSANOL - UNII:	9G10E216XY)	DOCOSANOL	10	0 mg in 1 g
In	active Ingre	edients					
			Ingredient Nam	e		Stre	ength
BE	NZYL ALCOHO	<b>L</b> (UNII: LKG8494)					
LIC	GHT MINERAL O	<b>IL</b> (UNII: N6K578					
PR	ROPYLENE GLYC	COL (UNII: 6DC9Q	(167V3)				
W	ATER (UNII: 0590	QF0KO0R)					
รบ	JCROSE DISTEA	RATE (UNII: 33X4	4X4B90S)				
รบ	JCROSE STEAR	<b>ATE</b> (UNII: 274KW	/0050M)				
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		acteristics		<b>C</b>			
	olor		WHITE				
	nape		Size				
Flavor Imprint Co							
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Co Pa	ontains ackaging	Pac	ckage Descripti		Marketing Start Date		eting End Date
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Cc Pa #	ackaging Item Code NDC:62332-	1 in 1 PACKAGE		on	Marketing Start Date		
C c P i # 1	ackaging Item Code NDC:62332-	1 in 1 PACKAGE	Type 0: Not a Combin	on	Marketing Start Date		
C c P i # 1 2	Ackaging Item Code NDC:62332- 682-01 NDC:62332-	1 in 1 PACKAGE 2 g in 1 TUBE; T 1 in 1 PACKAGE	Type 0: Not a Combin	<b>on</b> nation Product	Marketing Start Date 05/03/2022		
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C c P # 1 2 2 M	Ackaging Item Code NDC:62332- 682-01 NDC:62332- 682-03	1 in 1 PACKAGE 2 g in 1 TUBE; T 1 in 1 PACKAGE 2 g in 1 BOTTLE Product	ype 0: Not a Combin , PUMP; Type 0: Not ON ion Number or M Citation	on nation Product a Combination	Marketing Start Date 05/03/2022 05/03/2022 Marketing Start	Marke	Date eting End

Labeler - Alembic Pharmaceuticals Inc. (079288842)

Registrant - Alembic Pharmaceuticals Limited (871411532)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(62332-682), ANALYSIS(62332-682)					