

**DOCOSANOL- docosanol cream**  
**Cosette 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 0713-0353-02**

**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<sup>®</sup>.

\*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

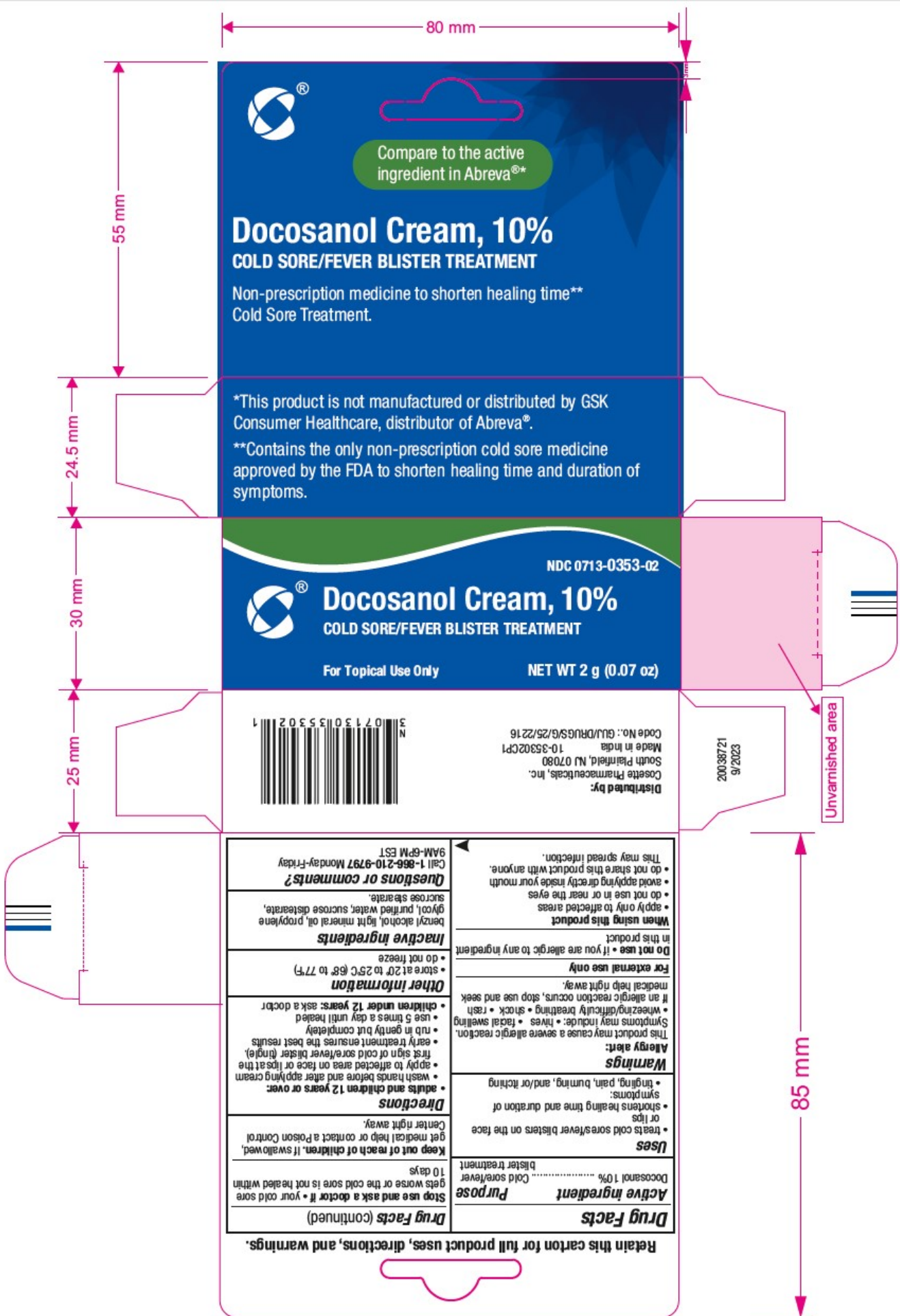
**Distributed by:**

**Cosette Pharmaceuticals, Inc.**

South Plainfield, NJ 07080

Made in India.

Code No.: GUJ/DRUGS/G/25/2216



80 mm

55 mm

24.5 mm

30 mm

25 mm

85 mm



Compare to the active ingredient in Abreva®\*

**Docosanol Cream, 10%**  
COLD SORE/FEVER BLISTER TREATMENT

Non-prescription medicine to shorten healing time\*\*  
Cold Sore Treatment.

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

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

NDC 0713-0353-02



**Docosanol Cream, 10%**  
COLD SORE/FEVER BLISTER TREATMENT

For Topical Use Only

NET WT 2 g (0.07 oz)



Distributed by:  
Cosette Pharmaceuticals, Inc.  
South Plainfield, NJ 07080  
1 0-35302CP1  
Code No.: GJ/DRUGS/G/25/22 16

20038721  
9/2023

Unvarnished area

Retain this carton for full product uses, directions, and warnings.

**Drug Facts**

**Active Ingredient**  
Docosanol 10% ..... Cold sore/fever blister treatment

**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**  
This product may cause a severe allergic reaction. Symptoms may include: • hives • facial swelling • wheezing/difficult breathing • shock • rash  
If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use** • If you are allergic to any ingredient in this product:  
• avoid applying directly inside your mouth  
• do not use in or near the eyes  
• apply only to affected areas

**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.

**Other information**  
• store at 20° to 25°C (68° to 77°)  
• 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

**Directions**  
• adults and children 12 years or over:  
• 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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Drug Facts (continued)**  
Stop use and ask a doctor if • your cold sore gets worse or the cold sore is not healed within 10 days

**Pump Pack****NDC 0713-0353-62****Docosanol Cream, 10%**

Compare to the active ingredient in Abreva®\*

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®.

\*\*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

**Distributed by:****Cosette Pharmaceuticals, Inc.**

South Plainfield, NJ 07080

Made in India.

Code No.: GUJ/DRUGS/G/25/2216



80 mm

55 mm

24.5 mm

30 mm

25 mm

85 mm



Compare to the active ingredient in Abreva®\*\*

**Docosanol Cream, 10%**  
COLD SORE/FEVER BLISTER TREATMENT

Non-prescription medicine to shorten healing time\*\*  
Cold Sore Treatment.



Portable Convenient Pump

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

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

MDC 0713-0353-62



**Docosanol Cream, 10%**  
COLD SORE/FEVER BLISTER TREATMENT

For Topical Use Only

NET WT 2 g (0.07 oz)



Distributed by:  
Coselte Pharmaceuticals, Inc.  
South Plainfield, NJ 07080  
Made in India  
10-35362CP1  
Code No.: Q1U/DHUS/0725/2216



Press Pump completely about 6 to 8 times to get first dose.

2008723  
9/2023

Unvarnished area

9AM-6PM EST  
Call 1-866-210-9797 Monday-Friday

**Questions or comments?**

**Active Ingredients**  
benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose disaccharate, sucrose stearate.

**Other Information**

- do not freeze
- store at 20° to 25°C (68° to 77°)
- 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

**Directions**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if • your cold sore gets worse or the cold sore is not healed within 10 days

**Drug Facts (continued)**

**Active Ingredient**  
Docosanol 10% Cold sore/fever blister treatment

**Purpose**  
Cold sore/fever blister treatment

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

**Warnings**  
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.



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## DOCOSANOL

docosanol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0713-0353
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCOSANOL</b> (UNII: 9G10E216XY) (DOCOSANOL - UNII:9G10E216XY)	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 DISTEARATE</b> (UNII: 33X4X4B90S)	
<b>SUCROSE STEARATE</b> (UNII: 274KW0050M)	

### 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:0713-0353-02	1 in 1 CARTON	01/04/2024	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0713-0353-62	1 in 1 CARTON	01/04/2024	
2		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215839	01/04/2024	

**Labeler** - Cosette Pharmaceuticals, Inc. (116918230)

**Registrant** - Alembic Pharmaceuticals Limited (650574663)

### Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(0713-0353) , ANALYSIS(0713-0353)

Revised: 1/2024

Cosette Pharmaceuticals, Inc.