

DOCOSANOL - docosanol cream
Encube Ethicals Private Limited

DOCOSANOL 10% CREAM

ACTIVE INGREDIENT(S)

Docosanol 10%

PURPOSE

Cold sore/fever blister treatment

USE(S)

- 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.

Syptoms 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 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

STORAGE

- store at 20°-25°C (68°-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 toll-free **1-833-285-4151** from Monday to Friday between 9 am to 6.30 pm

Manufactured by:

Encube Ethicals Private Limited

Plot No. C1, Madkaim Industrial Estate, Madkaim,

Post: Mardol, Ponda, Goa - 403 404, India

Distributed by:

Encube Ethicals, Inc.

200 Meredith Avenue, Suite 101A

Durham, NC 27713, USA

Thank you for purchasing Docosanol Cream, 10%. We hope that since Docosanol Cream shortens the healing time of cold sores, it helps you look and feel better faster. Please follow insert directions for proper use and refer to the information below.

You are not alone

An estimated one-in-five Americans is affected by cold sores each year. Most people

who experience them get two to three cold sore outbreaks each year. Just before and during an outbreak, the cold sore infection can be easily passed on to others. It is especially important to be aware of early warning signs that a cold sore is coming, and to be sure to avoid close physical contact when you have one.

Getting to the Root of the Problem

A blister, or cluster of blisters around your mouth, is caused by the cold sore virus. After the cold sore has healed, the virus stays dormant in your body but can be reactivated by everyday triggers like stress, sunlight, extreme hot or cold weather, colds and flu, lack of sleep, or menstruation.

The Sooner, the Better

A typical cold sore outbreak can last as long as seven to ten days. The sooner you begin using Docosanol Cream, 10%, the more effective the medicine will be. So for best results, use Docosanol Cream, 10% at the very start of the cold sore - when you feel the first sign of the tingle, redness, bump or itch.

Docosanol Cream, 10% is different from other over-the-counter cold sore products. Only Docosanol Cream, 10% contains 10% docosanol, which helps to shorten the healing time of cold sores and the duration of symptoms including tingling, pain, itching and burning.

FREQUENTLY ASKED QUESTIONS:

For Pump Bottle

How to use your Docosanol Cream, 10% Pump

- Adults and children 12 years and over can use Docosanol Cream, 10%.
- Docosanol Cream, 10% should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.
- If you wish, you can apply cosmetics such as lipstick over Docosanol Cream, 10%. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream, 10%.

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



STEP 1 - Wash your hands before and after treating the cold sore.

STEP 2 - Remove cap and press pump firmly. When first used, expect to press pump completely about 6-8 times before obtaining first dose.

STEP 3 - Rub in gently but completely 5 times a day until healed for maximum of 10 days.

STEP 4 - Place cap back on pump after each use.

For Tube

Who can use Docosanol Cream, 10%?

Adults and children 12 years and over can use Docosanol Cream, 10%.

How often can I apply Docosanol Cream, 10%?

Docosanol Cream, 10% should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.

Can I apply cosmetics on top of Docosanol Cream, 10%?

Yes, cosmetics such as lipstick may be applied over Docosanol Cream, 10%. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream, 10%.

PRINCIPAL DISPLAY PANEL

For Pump Bottle - Carton Label

NDC 21922-023-17

DOCOSANOL 10% CREAM

Cold Sore/Fever Blister Treatment

Only FDA Approved to Shorten Healing Time*

Cold Sore Treatment

NET WT

2g (0.07oz)

***Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.**

Drug Facts		Drug Facts (continued)	
Active ingredient Docosanol 10%...Cold sore/fever blister treatment	Purpose	<ul style="list-style-type: none"> 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. 	
Uses	<ul style="list-style-type: none"> treats cold sores/fever blisters on the face or lips shortens healing time and duration of symptoms: tingling, pain, burning, and/or itching 	<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 right away.</p>	
Warnings	<p>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</p> <ul style="list-style-type: none"> apply only to affected areas 	<p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years or over: <ul style="list-style-type: none"> 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 best results rub in gently but completely use 5 times a day until healed children under 12 years: ask a Doctor 	

Drug Facts (continued)	Drug Facts (continued)
Other information	Questions or comments?
<ul style="list-style-type: none"> store 20-25°C (68°-77°F) do not freeze <p>Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate</p>	<p>call toll-free 1-833-285-4151 from Monday to Friday between 9 am to 6:30 pm</p>

NDC 21922-023-17



Docosanol Cream, 10%

Cold Sore Treatment

Cold Sore / Fever Blister Treatment
Only FDA Approved Medicines to Shorten Healing Time*
NET WT 2 g (0.07 oz)

28 x 31 mm
Unvarnish Area
for Over coating

Mfg. Lic. No.: 361
 Manufactured by:
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Retain this carton for full product uses, directions and warnings.
 If you are not completely satisfied, save receipt and remaining product, and call us at 1-833-285-4151.

Portable Convenient Pump



DCE3A000

Area for batch coding

(For Reference Only)
 LOT: XXXXXXXXXX
 EXP: XXXXXX

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How to use your Docosanol Cream, 10% Pump
 - For Adults and Children 12 years and over
 - Docosanol Cream, 10% should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.

- If you wish, you can apply cosmetics such as lipstick over Docosanol Cream, 10%. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream, 10%.

Press Pump completely about 5-8 times to get first dose.

STEP 1 - Wash your hands before and after treating

STEP 2 - Rub in gently but completely 5 times a day until healed for maximum of 10 days.

STEP 3 - Remove cap and press pump firmly. When first used, expect to press pump completely about 5-8 times before obtaining first dose.

STEP 4 - Place cap back on pump after each use.

For more information: Call us at 1-833-285-4151.

NDC 21922-023-17
Docosanol Cream, 10%
 NET WT 2 g (0.07 oz)



***Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.**

Drug Facts Active ingredient Docosanol 10%...Cold sore/fever blister treatment Purpose Cold sore/fever blister treatment		Drug Facts (continued) <ul style="list-style-type: none"> 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. 	
Uses • treats cold sores/fever blisters on the face or lips • shortens healing time and duration of symptoms: • tingling, pain, burning, and/or itching		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.	
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.		Directions <ul style="list-style-type: none"> adults and children 12 years or over: <ul style="list-style-type: none"> 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 best results rub in gently but completely use 5 times a day until healed children under 12 years: ask a Doctor 	
For external use only Do not use • if you are allergic to any ingredient in this product When using this product <ul style="list-style-type: none"> apply only to affected areas 		Drug Facts (continued) Other information <ul style="list-style-type: none"> store 20-25°C (68°-77°F) do not freeze 	
Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate		Drug Facts (continued) Questions or comments? call toll-free 1-833-285-4151 from Monday to Friday between 9 am to 6.30 pm	

NDC 21922-023-17



Docosanol Cream, 10%

Cold Sore Treatment

Cold Sore / Fever Blister Treatment

Only FDA Approved Medicines to Shorten Healing Time*

NET WT 2 g (0.07 oz)

28 x 31 mm
Unvarnish Area
for Over coating

Mfg. Lic. No.: 361
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Retain this carton for full product uses, directions and warnings.

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Portable Convenient Pump



N 31 21922102317 6

DCE3A/00

Area for batch coding

(For Reference Only)
 LOT: XXXXXXXXXX
 EXP: XXXXXX

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How to use your Docosanol Cream, 10% Pump

- For Adults and Children 12 years and over

- Docosanol Cream, 10% should be used five times a day until the cold sore is healed. Apply it directly to the cold sore at the first sign of a tingle, redness, bump or itch for best results.

- If you wish, you can apply cosmetics such as lipstick over Docosanol Cream, 10%. However, use a separate applicator, like a cotton swab, to apply cosmetics over an unhealed cold sore to avoid spreading the infection. For best results, remove any cosmetics prior to applying Docosanol Cream, 10%.

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



STEP 1 - Wash your hands before and after treating the cold sore.

STEP 2 - Remove cap and press pump firmly. When first used, expect to press pump completely about 6-8 times before obtaining first dose.

STEP 3 - Rub in gently but completely 5 times a day until healed for maximum of 10 days.

STEP 4 - Place cap back on pump after each use.

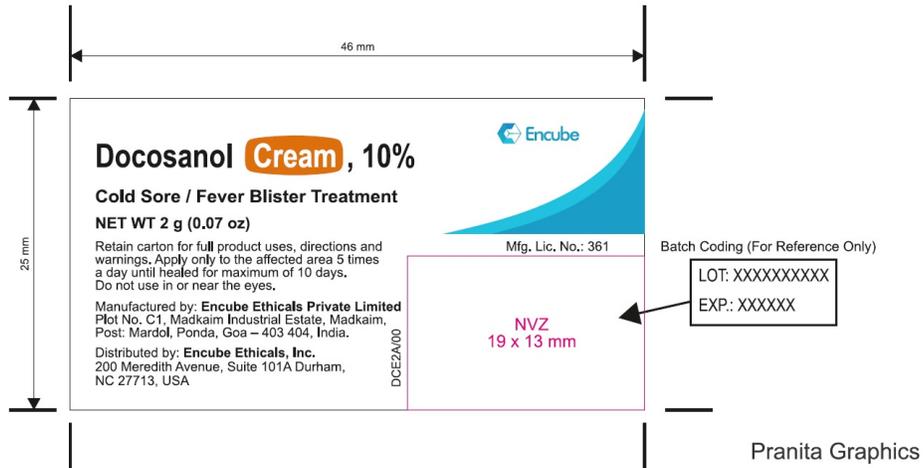
For more information: Call us at 1-833-285-4151.

NDC 21922-023-17

**Docosanol
Cream, 10%**

NET WT 2 g (0.07 oz)

For Pump Bottle - Bottle Label
NDC 21922-023-17
DOCOSANOL 10% CREAM
Cold Sore/Fever Blister Treatment
Only FDA Approved to Shorten Healing Time*
Cold Sore Treatment
NET WT
2g (0.07oz)



 Encube	Product	Docosanol 10% Cream 2 g Label			Colours Used
	Artwork Code	DCE2A/00		Pantone 158 C	
	SAP Code	NA		Pantone 639 C	
	Pharma code	9		Pantone 311 C	
	Size (Dia)	46 x 25 mm		Black	
	Material	–		Pantone Process Blue C	
	Grammage	NA		Pantone 312 C	
	Spl Req.	NA	<input type="checkbox"/>	Base White Colour	
	History	New Artwork	<input type="checkbox"/>	Keyline (not to print)	
				Minimum Font Size: 3 pt	
			Maximum Font Size: 6.111 pt		
			NV/22.07.2020		
Prepared by:	Reviewed by:			Approved by:	
Pkg. Devp. Dept.	Production Dept.	Engineering Dept.	RA (HO)	QA (GOA)	Head Pkg. Devp.

For Tube - Carton
NDC 21922-023-18
DOCOSANOL 10% CREAM
Cold Sore/Fever Blister Treatment
Only FDA Approved to Shorten Healing Time*
Cold Sore Treatment
NET WT
2g (0.07 oz)

***Docosanol Cream, 10% contains the only OTC medicine approved by the FDA to shorten healing time and duration of symptoms.**

Drug Facts		Drug Facts (continued)	
Active ingredient Docosanol 10%...Cold sore/fever blister treatment	Purpose Cold sore/fever blister treatment	<ul style="list-style-type: none"> 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. 	
Uses • treats cold sores/fever blisters on the face or lips • shortens healing time and duration of symptoms: • tingling, pain, burning, and/or itching		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.	
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.		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	
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			

Drug Facts (continued)	Drug Facts (continued)
Other information • store 20-25°C (68°-77°F) • do not freeze	Questions or comments? call toll-free 1-833-285-415 from Monday to Friday between 9 am to 6.30 pm
Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate and sucrose stearate	

NDC 21922-023-18



Docosanol Cream, 10%

Cold Sore Treatment

Cold Sore / Fever Blister Treatment

Only FDA Approved Medicines to Shorten Healing Time*

NET WT 2 g (0.07 oz)

28 x 31 mm
Unvarnish Area
for Over coating

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DCFE:BA:ND

Area for batch coding

(For Reference Only)
LOT: XXXXXXXXXX
EXP: XXXXXX

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Frequently Asked Questions:

Who can use Docosanol Cream, 10%?
Adults and children 12 years and over can use Docosanol Cream, 10%.

How often can I apply Docosanol Cream, 10%?
Docosanol Cream, 10% should be used five times a day until the cold sore is healed.

Can I apply cosmetics on top of Docosanol Cream, 10%?
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Drug Facts		Drug Facts (continued)	
Active ingredient Docosanol 10%...Cold sore/fever blister treatment	Purpose	<ul style="list-style-type: none"> 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. 	
Uses		Stop use and ask a doctor if	
<ul style="list-style-type: none"> treats cold sores/fever blisters on the face or lips shortens healing time and duration of symptoms: tingling, pain, burning, and/or itching 		<ul style="list-style-type: none"> your cold sore gets worse or the cold sore is not healed within 10 days. 	
Warnings		Keep out of reach of children.	
Allergy alert		If swallowed, get medical help or contact a Poison Control Center right away.	
<p>This product may cause a severe allergic reaction. Symptoms may include: • hives • facial swelling</p> <ul style="list-style-type: none"> wheezing/difficulty breathing shock rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p>		Directions	
For external use only		<ul style="list-style-type: none"> 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 	
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Drug Facts (continued)		Drug Facts (continued)	
Other information		Questions or comments?	
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NDC 21922-023-18

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Cold Sore / Fever Blister Treatment

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NET WT 2 g (0.07 oz)



Cold Sore Treatment

28 x 31 mm
Unvarnish Area
for Over coating

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DCE3B/00

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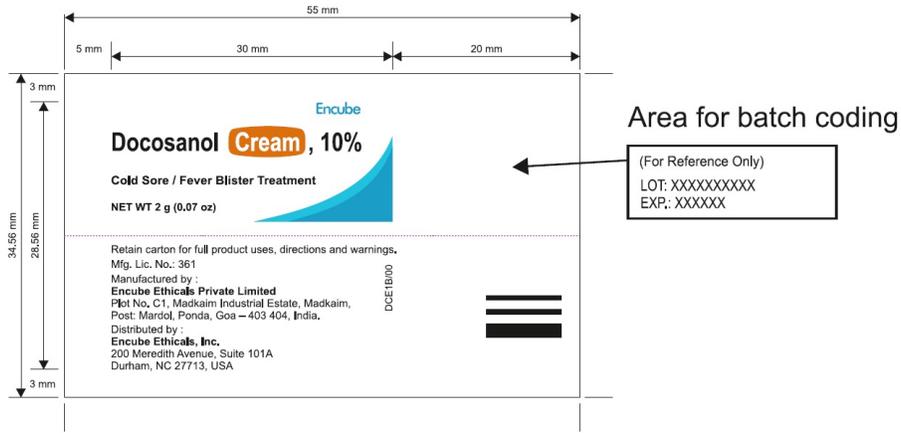
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Cold Sore/Fever Blister Treatment
Only FDA Approved to Shorten Healing Time*
Cold Sore Treatment
NET WT
2g (0.07 oz)**



Pranita Graphics

 Encube	Product	Docosanol Cream, 10% 2 g Tube			Colours Used
	Artwork Code	DCE1B/00			 Pantone 158 C
	SAP Code	-			 Pantone 639 C
	Pharma code	8			 Pantone 311 C
	Size (Dia)	11 X 55 mm			 Black
	Material	Al Tube			
	Grammage	NA			
	Spl Req.	NA			<input type="checkbox"/> Base White Colour
	History	New Artwork			<input type="checkbox"/> Keyline (not to print)
					Minimum Font Size: 3 pt
				Maximum Font Size: 6.803 pt	
				NV/22.07.2020	
Prepared by:	Reviewed by:			Approved by:	
Pkg. Devp. Dept.	Production Dept.	Engineering Dept.	RA (HO)	QA (GOA)	Head Pkg. Devp.

DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-023
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: 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:21922-023-18	1 in 1 PACKAGE	10/10/2022	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21922-023-17	1 in 1 PACKAGE	10/10/2022	
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	ANDA212385	10/10/2022	

Labeler - Encube Ethicals Private Limited (915834105)

Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	ANALYSIS(21922-023) , LABEL(21922-023) , MANUFACTURE(21922-023) , PACK(21922-023)

Revised: 10/2022

Encube Ethicals Private Limited