

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-941**

**FINAL PRINTED LABELING**

"Drug Facts" for the outer carton label (bottom half)

**Abreva**

Retain outer carton  
for full product uses,  
directions and  
warnings

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**Drug Facts**

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**Active ingredient**

**Purpose**

Docosanol 10% ..... Cold sore/fever blister treatment

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**Uses**

- treats cold sores/fever blisters on the face or lips
- shortens healing time

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**Warnings**

- For external use only

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**Do not use**

- if you are allergic to any ingredient in this product

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**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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**Stop use and ask a doctor if**

- your cold sore gets worse or the cold sore is not healed within 10 days

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**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

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**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

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**Other information** ● store at 20°-25°C (68°-77°F) ● do not freeze

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**Inactive ingredients:** benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate, sucrose stearate

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**Questions?** call 1-800-245-1040 weekdays

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[Bar Code]

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Outer carton label (top half)

NEW  
Cold Sore/Fever Blister Treatment

Abreva

- Shortens healing time
- Cream formula- dries clear

Abreva

Abreva  
Docosanol 10% Cream

Cold Sore/Fever Blister Treatment

NET WT 2.0g (.07 oz)

LOT  
EXP

Immediate tube label

Abreva  
Docosanol 10% Cream  
Cold Sore/Fever Blister Treatment

EXP

NET WT 2.0g (.07 oz)

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

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LOT

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# APPROVED

JUL 25 2000

## Abreva

Apply the ointment  
to the painful area  
5 times a day  
after meals

### Drug Facts

Active Ingredient	Purpose
Docosanol 1%	Cold sores and cold sore outbreaks

**Uses** - Treats cold sores (herpes simplex virus) on the lips or face.  
 - Relieves itching, pain, burning, and/or stinging.

### Warnings

- For external use only
- Do not use if you are allergic to any ingredients in this product
- When using this product:
  - Apply only to affected areas
  - Do not use to treat the eyes
  - Do not use on broken skin or on the lips of the first stage of cold sores
  - Do not use on the genital area
- Apply only once daily 5 times a day
- 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 of age or older:
  - Apply 5 times a day to the affected area
  - Apply to the affected area on the lips or face at the first sign of cold sores
  - Apply 5 times a day 5 times a day
  - Use 5 times a day 5 times a day
  - Use 5 times a day 5 times a day

**Other information** - Keep out of reach of children.  
**Keep out of reach of children.**  
 For more information, please contact your pharmacist, physician, or poison control center.  
 Questions? Call 1-877-200-6000

tingling, pain, burning, and/or stinging  
 (this is a sub-note, under "stinging, burning, tingling, pain, and duration of symptoms")



Manufactured by  
 Pharmacia Corporation  
 Kalamazoo, MI 49001  
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Abreva

Abreva

Abreva

Abreva

NEW Cold Sore Treatment

**Abreva**  
Dermatological Cream

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

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**Abreva**  
Dermatological Cream  
NET WT 2.0g (0.07 oz)

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

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200%

JUL 25 2000

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Abreva 12/06/08 10:33