ANBESOL COLD SORE THERAPY- allantion, benzocaine, camphor, petrolatum ointment
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Allantoin 1%

Benzocaine 20%

Camphor 3%

White petrolatum 64.9%

Purposes

Skin protectant

Fever blister/cold sore treatment

Fever blister/cold sore treatment

Skin protectant

Uses

1. temporarily relieves pain associated with fever blisters and cold sores
2. relieves dryness and softens fever blisters and cold sores

Warnings

METHEMOGLOBINEMIA WARNING

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

1. pale, gray, or blue colored skin (cyanosis)
2. headache
3. rapid heart rate
4. shortness of breath
5. dizziness or lightheadedness
6. fatigue or lack of energy

For external use only

Allergy alert

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Do not use

1. on deep or puncture wounds
2. on animal bites
3. on serious burns
4. for teething
5. in children under age 2

When using this product

1. avoid contact with the eyes
2. do not exceed recommended dosage

Stop use and ask a doctor if

1. condition worsens
2. symptoms persist for more than 7 days
3. symptoms clear up and occur again within a few days

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

Directions

1. to open tube, cut tip of the tube on score mark with scissors
2. adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily
3. children under 12 years of age: adult supervision should be given in the use of this product
4. children under 2 years of age: do not use

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

aloe barbadensis leaf extract, benzyl alcohol, butylparaben, glyceryl monostearate, isocetyl stearate, menthol, methylparaben, mineral oil, propylparaben, sodium lauryl sulfate, vitamin E, white wax

Questions or comments?

Call weekdays 9AM to 5PM EST at **1-888-797-5638**

PRINCIPAL DISPLAY PANEL - 9 g Tube Blister Pack Label

ointment
WITH
Vitamin E
& Aloe

See new warnings information

Anbesol®
Fever Blister/Cold Sore Treatment

Cold Sore THERAPY

MAXIMUM
STRENGTH

DOCTOR
RECOMMENDED

Instant
Pain Relief

1. Cold Sores and
   Fever Blisters
2. Moisturizes While It
   Treats and Protects

NET WT 0.33 OZ (9 g)

Safety Sealed Tube:
Do Not Use if tube tip is cut prior to opening.

See new warnings information

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READ AND KEEP CARD FOR COMPLETE WARNINGS AND INFORMATION

AREA FOR LOT, EXPIRATION DATE AND COUNTRY OF ORIGIN

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Drug Facts (continued)

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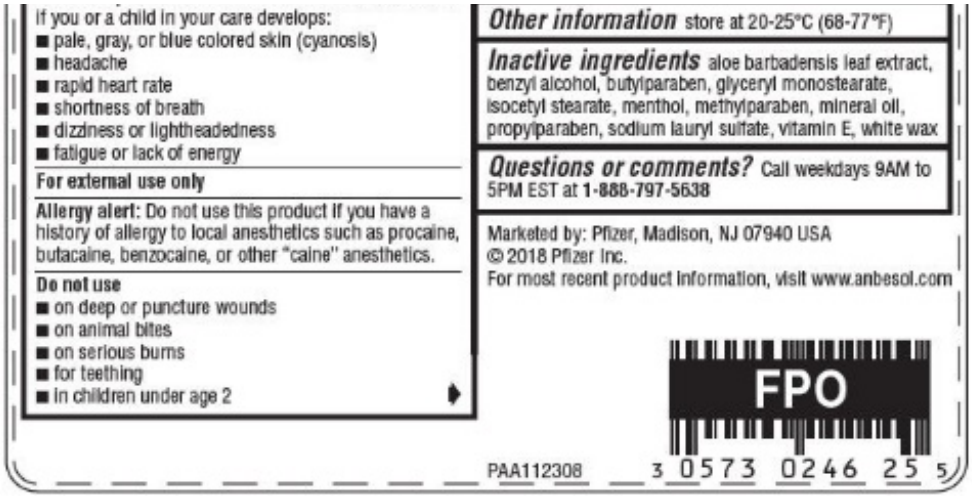

ANBESOL COLD SORE THERAPY

allantion, benzocaine, camphor, petrolatum ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	10 mg in 1 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	30 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	649 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics			
Color	WHITE (White ointment)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0246-25	1 in 1 BLISTER PACK	05/09/2006	06/21/2010
1		9 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-0246-26	1 in 1 BLISTER PACK	09/15/2008	
2		9 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
OTC monograph not final	part348	05/09/2006	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 11/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC