ORALABS COLD SORE TREATMENT- benzocaine ointment
OraLabs

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 ingredient

Benzocaine

Purpose

Cold Sore/Fever Blister Treatment/Pain Reliever

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Uses

For treatment of cold sores/fever blisters on the face and lips

Warnings

For external use only: Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a physician.

Allergy Alert: Do not use if you are allergic to any of the ingredients in this product.

When using this product avoid contact with eyes. Use only as directed.

Stop use and ask a doctor if the condition gets worse. Do not use longer than 1 week unless directed by a doctor.

Directions

Clean the affected

Adults and children 2 years of age and older: Apply to affected area not more than 4 times daily

Children under 2 years of age: consult a physician

Rub in gently – Applies clear

Wash hands before and after applying cream

Do not share this product with anyone

Inactive Ingredients

Benzyl Alcohol, Docosanol, Mineral Oil, Propylene Glycol, Sucrose Stearate, Tocopherol, Water.

Package/Label Principal Display Panel

ORALABS COLD SORE TREATMENT

benzocaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63645-162
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5.00 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	2.00 mg in 1 g
DOCOSANOL (UNII: 9G1OE216XY)	10 mg in 1 g
BENZYL ALCOHOL (UNII: LKG8494WBH)	9.00 mg in 1 g
SUCROSE STEARATE (UNII: 274KW0O50M)	5.00 mg in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	4.99 mg in 1 g
WATER (UNII: 059QF0KO0R)	64 mg in 1 g

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-162-04	1 g in 1 CONTAINER; 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	08/01/2014	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-162) , LABEL(63645-162)

Revised: 9/2014 OraLabs