MAKESENSE PAIN RELIEF- benzocaine gel Cherry Hill Sales Co

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 20%

Purpose

Oral Pain Reliever

Uses

for the temporary relief of pain associated with:

■ toothache ■ canker sores ■ cold sores ■ fever blisters ■ minor dental procedures

Warnings

Allergy alert: do not use this product if your child has a history of allergy to local anesthetics such as procaine, butacaine or other "caine" anesthetics

Do not use

■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider.

When using this product

■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician

Stop use and aska doctor if

■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children

In case of overdose or allergic reaction get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 2 years of age and older: cut open tip of tube apply to affected area up to 4 times daily or as directed by a dentist or physician children under 12 years of age should be supervised using this product for infants under 2 years of age, ask a doctor or health care provider

Other information

■ store at 59 to 77F (15-25C) ■ do not use if tube tip is cut prior to opening

Inactive ingredients

Methylparaben, Mineral Oil, Ozocerite, Petrolatum, Propanediol, Propylparaben

Package Label



MAKESENSE PAIN RELIEF

benzocaine gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-207	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	20 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
MINERAL OIL (UNII: T5L8T28FGP)			
CERESIN (UNII: Q1LS2UJO3A)			
PETROLATUM (UNII: 4T6H12BN9U)			
PROPANEDIOL (UNII: 5965N8W85T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69020-207-14	14 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	07/15/2014		

Labeler - Cherry Hill Sales Co (145959768)

Establishment			
Name	Address	ID/FEI	Business Operations
Ausmetics Daily Chemicals (Guangzhou) Co. Ltd.		529836561	manufacture(69020-207)

Revised: 7/2014 Cherry Hill Sales Co