MAKESENSE JUNIOR 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 7.5%

Purpose

Oral Pain Reliever

Uses

for the temporary relief of sore gums due to teething in children 2 years of age and older. For use in children under the age of 2, consult a physician or healthcare provider.

Warnings

Allergy alert: do not use this product if your baby 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 ask a dentist or 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

■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of MakeSense Junior Teething Gel and spread over gums ■ apply to affected area up to 4 times daily or as directed by a dentist or physician ■ 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 JUNIOR PAIN RELIEF

benzocaine gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-206	
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	7.5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
METHYLPARABEN (UNII: A218 C7H19 T)			
MINERAL OIL (UNII: T5L8T28FGP)			
CERESIN (UNII: Q1LS2UJO3A)			
PETROLATUM (UNII: 4T6 H12BN9 U)			
PROPANEDIOL (UNII: 5965N8W85T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 1	NDC:69020-206-14	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)

Revised: 7/2014 Cherry Hill Sales Co