ORAL PAIN RELIEF- oral pain reliever gel
Kareway Product, Inc.

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

Warnings

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

more than directed for more than 7 days unless told to do so by a dentist or doctor

Stop use and ask a doctor if

swelling, rash or fever develops; irritation, pain or redness persists or worsens; symptoms do not improve in 7 days

Keep out of reach of children:

in case of overdose, get medical help or contact a Poison Control Center right away

Directions

Directions do not use if tube tip is cut prior to opening; cut open tip of tube on score mark

Adults and children 2 years of age and over Apply a small amount of product to the cavity and around gum surrounding the teeth.
Use up to 4 times daily or as directed by a dentist or doctor

Children under 12 years of age Should be supervised in the use of this product

Children under 2 years of age Ask a dentist or doctor

Other information

This preparation is intended for use in case of toothache, only as a temporary expedient until a dentist can be consulted;

do not use continuously

Inactive ingredients

Inactive ingredients polyethylene glycol, glycerin, sodium saccharin, sorbic acid, flavor

Active ingredient (in each gram)

Benzocaine 20%

Purpose

Oral Pain Reliever

Uses

temporarily relieves pain due to toothaches

Orajel gel

Instant Pain Relief

for TOOTHACHE

MAXIMUM STRENGTH

NE WT 0.42 OZ (11.9 g) ORAL PAIN RELIEVER BENZOCAINE 20%

ORAL PAIN RELIEF

oral pain reliever gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67510-0058-4	1 in 1 CARTON	07/17/2011	
1		11.9 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	part356	07/17/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 12/2017 Kareway Product, Inc.