

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

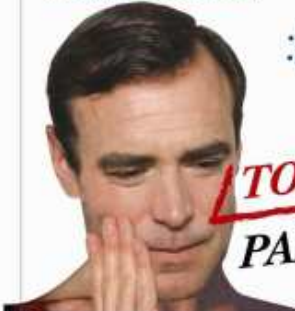
Instant Pain Relief

for TOOTHACHE

MAXIMUM STRENGTH

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

MAXIMUM STRENGTH



- Alivia el dolor oral
- Alivia rápido de dolor de muelas

**FAST
TOOTHACHE
PAIN RELIEF**

Pure-Aid™

Compare to Orajel® active ingredient*

- Fast toothache relief
- Relieves oral pain

KAREWAY

MAXIMUM STRENGTH

BENZOCAINE 20%

Oral Pain Relief

Fast Toothache Pain Relief

NET 0.42 oz (11.9g)

BENZOCAINE 20%

Oral Pain Relief
Fast Toothache Pain Relief

BENZOCAINE 20%

Oral Pain Relief

Fast Toothache Pain Relief



LOT & EXP.

Made in Korea

Drug Facts(Continued)
 around gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor.
Children under 12 years
 Should be supervised in the use of this product.
Children under 2 years
 Ask a dentist or doctor.
Other information
 This preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted. Do not use continuously.
Inactive ingredients Polyethylene glycol, Glycerin, Sodium saccharin, Sorbic acid, Flavor.
 *This product is not manufactured or distributed by DEL PHARMACEUTICALS, owner of the registered trademark Orajel®.
 Exclusively distributed by:
 Kareway Product Inc, Gardena, CA 90248

Drug Facts
Active ingredient (in each gram) Benzocaine 20%
Purpose Oral Pain Reliever
 Use temporarily relieves pain due to toothaches.
Warnings
 Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, tetracaine, 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
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions
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 ■ cut open tip of tube on score mark
 Apply a small amount of product to the cavity and

KAREWAY

Oral Pain Relief
Fast Toothache Pain Relief

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.