

ORAL PAIN RELIEF- oral pain reliever gel

Discount Drug Mart, 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

Active ingredient (in each gram)

Benzocaine 20%

Purpose

Oral Pain Reliever

Uses

for the temporary relief of pain due to

- toothaches
- canker sores
- minor injury of the mouth and gums
- minor irritation of the mouth and gums caused by dentures

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

Flammable: keep away from fire or flame. Avoid smoking during application and until this product has dried.

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 or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions

Directions cut open tip of tube

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

Inactive ingredients

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

Other Information

- do not use if tube tip is cut prior to opening
- 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

Discount Drug Mart Oral Pain Relief



MAXIMUM STRENGTH FAST TOOTHACHE PAIN RELIEF

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

Compare to Orajel®
active ingredient*

- Fast toothache relief
- Relieves oral pain

MAXIMUM STRENGTH

BENZOCAINE 20%

Oral Pain Relief

Fast Toothache Pain Relief

MAXIMUM STRENGTH

BENZOCAINE 20%

Oral Pain Relief

Fast Toothache Pain Relief

NET 0.42 oz (11.9g)

LOT & EXP.

BENZOCAINE 20%

Oral Pain Relief

Fast Toothache Pain Relief

SATISFACTION GUARANTEED
IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256



Made in Korea

<p>Drug Facts (continued)</p> <p>Directions • Cut open tip of tube and around gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor.</p> <p>Children under 12 years of age should be supervised in the use of this product.</p> <p>Children under 2 years of age Ask a dentist or doctor</p>		<p>Other information</p> <ul style="list-style-type: none"> do not use if tube tip is cut prior to opening. 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. <p>Inactive ingredients flavor, glycerin, polyethylene glycol, sodium saccharin, sorbic acid</p> <p>Warnings</p> <ul style="list-style-type: none"> do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. Flammable: keep away from fire or flame. Avoid smoking during application and until this product has dried. Do not use more than directed for more than 7 days unless directed by a dentist or doctor. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> swelling, rash, or fever develops irritation, pain or redness persists or gets worse symptoms do not improve in 7 days <p>Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away</p>
<p>Drug Facts</p> <p>Active ingredient (in each gram) Benzocaine 20% Purpose Oral pain reliever</p> <p>Uses</p> <ul style="list-style-type: none"> for the temporary relief of pain due to toothaches canker sores minor injury of the mouth and gums minor irritation of the mouth and gums caused by dentures 		<p>Warnings</p> <ul style="list-style-type: none"> do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. Flammable: keep away from fire or flame. Avoid smoking during application and until this product has dried. Do not use more than directed for more than 7 days unless directed by a dentist or doctor. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> swelling, rash, or fever develops irritation, pain or redness persists or gets worse symptoms do not improve in 7 days <p>Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away</p>



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:53943-996
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	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:53943-996-42	1 in 1 CARTON	11/09/2015	
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	11/09/2015	

Labeler - Discount Drug Mart, Inc. (047741335)

Revised: 12/2017

Discount Drug Mart, Inc.