

QUALITY CHOICE MAXIMUM STRENGTH ORAL PAIN RELIEVING- benzocaine gel
Chain Drug Marketing Association 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.

QC Maximum Strength Oral Analgesic 0.42oz 95362 (2019) - ZDP

Active ingredient Purpose

Benzocaine 20%.....Oral pain reliever

Uses

- for the temporarily relieves pain due to:
- toothache
- canker sores
- gum pain
- denture pain
- cheek bites

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: do not use this product if your child has 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 directed by a doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

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

If pregnant or breast-feeding , ask a health professional before use.

Keep out of reach of children. In cases of overdose, get medical help or contact a Poison Control Center right away.

Directions

Remove cap and cut tip of tube. Apply a small amount of

Adults and children 2 years of age and older.

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.

Do not use.

Other information

- store at room temperature 20° to 25°C (68° to 77°F)
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist or doctor can be consulted
- do not use continuously

Inactive ingredients

glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

Distributed By C.D.M.A., Inc.

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Made in China



IMAGE
PLACEHOLDER

QUALITY CHOICE MAXIMUM STRENGTH ORAL PAIN RELIEVING

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-477
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 4000 (UNII: 4R4HF16D95)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-477-11	1 in 1 CARTON	08/09/2019	
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	08/07/2019	

Labeler - Chain Drug Marketing Association Inc (011920774)

Revised: 8/2019

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