

QUALITY CHOICE ORAL PAIN RELIEF- benzocaine 20%, benzalkonium chloride 1% gel

Quality Choice (CHAIN DRUG MARKETING ASSOCIATION)

Quality Choice Oral Pain Relief

Active ingredients

Benzocaine 20%

Benzalkonium Chloride 0.1%

Purpose

Oral pain reliever

Antiseptic

Use

- for the temporary relief of pain due to toothaches
- to help protect against infection in minor oral irritation

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 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 directed by a physician or healthcare provider
- for teething
- in children under 2 years of age

Stop use and ask a physician 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 (1-800-222-1222)

Directions

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

- this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted
- do not use continuously
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying
- do not use if tube seal under cap is broken
- store at 20-25C (68-77F)

Inactive ingredients

glycerin, PEG 400, propylene glycol, sorbitol, sodium saccharine, sorbic acid, sodium polyacrylate, strawberry flavor, water

Questions or comments?

TOLL FREE **800-935-2362**





Distributed by CIMA, Inc.
 Norv, MI 48376
 www.cimapharm.com
 Dues: 800-838-2362

Made in India
 Model 89-21942
 82-89077 03/24
 YC890072



78.00 mm

Keep out of reach of children. In case of overdose or adverse reaction, get medical help or contact a Poison Control Center (1-800-368-1329) right away.

Warnings: Do not use if you are allergic to any of the ingredients listed below. Do not use if you have had an allergic reaction to any of the ingredients listed below. Do not use if you have had an allergic reaction to any of the ingredients listed below.

Directions: See the back of the package for complete directions.

Other information: This product contains benzocaine, benzalkonium chloride, and other inactive ingredients.

Keep out of reach of children. In case of overdose or adverse reaction, get medical help or contact a Poison Control Center (1-800-368-1329) right away.

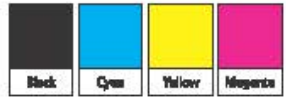

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Packaging / Printing / Packing			
Packaging Type	Folded hanging box	Ink Type	Standard
Print Size	7.253" W	Process Colors	CMYK
	7.5591 H	Pantone Colors	PMS 80C/83C
Stock	.016 SBS	Pantone Colors	-
Diecut	Yes	Coating	Gloss
Recycled Content	No	No. Sides Printed	1 Side
Binularity	Score, Fold, & Glue	DieLine CAD \$	-
			
Instructions: Follow 89-21942 SPECS Stamp LOT and EXP on box			

QUALITY CHOICE ORAL PAIN RELIEF

benzocaine 20%, benzalkonium chloride 1% gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-035
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-035-12	1 in 1 CARTON	04/01/2024	
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 Drug	M022	04/01/2024	

Labeler - Quality Choice (CHAIN DRUG MARKETING ASSOCIATION) (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Astonea Labs Private Label		878533295	manufacture(83324-035)

Revised: 4/2024

Quality Choice (CHAIN DRUG MARKETING ASSOCIATION)