

ORAL PAIN RELIEF- benzocaine gel
ALAINA HEALTHCARE PRIVATE LIMITED

MAXIMUM STRENGTH ORAL PAIN RELIEF

Drug Facts

Active ingredients

Purpose

Benzocaine 20%.....Oral pain reliever

Uses

- temporarily relieves pain associated with the following mouth and gum irritations:
- toothache
- canker sores
- minor dental procedures
- dentures
- sore gums
- braces

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:

- for teething
- in children under 2 years of age

When using this product:

- avoid contact with the eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor/dentist

Stop use and ask doctor if

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

Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions:

adults and children 2 years of age and over	apply a pea-size amount to the affected area up to 4 times daily or as directed by a doctor/dentist
children under 12 years of age	adult supervision should be given in the use of this product
children under 2 years of age	do not use

- For denture irritation:
- apply thin layer to the affected area
- do not reinsert dental work until irritation/pain is relieved
- rinse mouth well before reinserting

Other information

- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive Ingredients

benzyl alcohol, carbomer, D&C red no. 33, FD&C blue no. 1, FD&C yellow no. 6, glycerin, natural flavor, polyethylene glycol, polysorbate 80, propylene glycol, sodium saccharin, sorbic acid

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH

ORAL PAIN RELIEF GEL

FAST ACTING

Benzocaine 20% pain relieving gel

NET WT 0.5 OZ (14g)

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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Made in India

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FAST ACTING

Benzocaine 20% pain relieving gel

MAXIMUM STRENGTH FAST ACTING ORAL PAIN RELIEF

• Toothache • Gum Pain • Canker Sores • Denture Pain

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Drug Facts (continued)

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Do not use if the printed safety seal on the carton is broken or missing
READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

ORAL PAIN RELIEF
benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73492-717
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73492-717-50	1 in 1 CARTON	12/08/2023	
1		14 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	12/08/2023	

Labeler - ALAINA HEALTHCARE PRIVATE LIMITED (858720927)

Establishment

Name	Address	ID/FEI	Business Operations
ALAINA HEALTHCARE PRIVATE LIMITED		858720927	manufacture(73492-717)