ORAL PAIN RELIEF- benzocaine and benzalkonium chloride gel
Anicare Pharmaceuticals Pvt. Ltd

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.

Oral Pain Relief Gel

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 reduce 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 lightheadness
• 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 or other "caine" anesthetics

Do not use

■ more than directed

■ for more than 7 days unless directed by a physician or healthcare provider

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.

Directions

■ adults and children 2 years of age and over: apply a small amount of the 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 ot toothache, only as a temporary expedient until a physican 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, missing or if the tube tip is cut prior to opening

Inactive ingredients

ammonium glycyrrhizate, flavor, polyethylene glycol, sodium saccharin, sorbic acid, purified water, FD&C Yellow#5, FD&C Red#40

Package Label

Oral Pain Relief Gel

NET WT. 0.5 oz (14 g)

ORAL PAIN RELIEF

benzocaine and benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47046-156
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-156-02	1 in 1 CARTON	12/09/2020	
1	NDC:47046-156-01	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 not final	part356	12/09/2020	

Labeler - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-156)

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd