

NBE ANBESOL- benzocaine gel
Walgreens

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.

5820622 Walgreens NBE Anbesol Gel

Benzocaine 20%

Oral anesthetic

temporarily relieves pain associated with mouth and gum irritations

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 told to do so by a dentist or doctor * for teething * in children under 2 years of age

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 * allergic reaction occurs

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

to open tube, cut tip of tube on score mark * adults and children 2 years of age and older: apply to affected area up to 4 times daily or as directed by a dentist/doctor * 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 a thin layer to the affected area; do not reinsert dental work until irritation/pain is relieved; rinse mouth well after reinserting

store at 20-25C (68-77F). Do not refrigerate.

blue 1, carbomer, flavor, glycerin, polyethylene glycol, propylene glycol, red 40, sodium saccharin, sorbic acid, water, yellow 10



NBE ANBESOL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0316
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBIC ACID (UNII: X045VJ989B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

GLYCERIN (UNII: PDC6A3C0OX)

Product Characteristics

Color	red (Reddish-orange to slightly brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0316-69	1 in 1 CARTON	06/22/2022	
1		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	04/30/2022	

Labeler - Walgreens (008965063)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(0363-0316) , pack(0363-0316)

Revised: 1/2023

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