3X MEDICATED MOUTH SORE GEL- 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.

5820605 Walg 3x Gel

Benzocaine 20%

Menthol 0.1%

Zinc chloride 0.15%

Oral pain reliever

Oral pain reliever

Oral astringent

temporarily relieves pain caused by * canker sores * cold sores * fever blisters * minor irritation or injury of the mouth and gums

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 (1-800-222-1222).

cut open tip of tube on score mark * do not use if tip is cut prior to opening * adults and children 2 years of age and older: apply to affected area 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

allantoin, carbomer, disodium EDTA, flavor, polyethylene glycol, polysorbate 60, propylene glycol, pvp, sodium saccharin, sorbic acid, stearyl acohol, water

3X MEDICATED MOUTH SORE GEL

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-1605
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

POLYSORBATE 60 (UNII: CAL22UVI4M)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
SORBIC ACID (UNII: X045WJ989B)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	yellow (Clear to yellow tint)	**Score**	
Shape		**Size**	
Flavor	WINTERGREEN	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1605-19	1 in 1 CARTON	10/20/2021	
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	10/20/2021	

Labeler - Walgreens (008965063)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(0363-1605)

Revised: 1/2023 Walgreens