ORAJEL 3X MEDICATED FOR ALL MOUTH SORES- benzocaine, menthol, zinc chloride gel
Church & Dwight Co., Inc.

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.

Orajel 3X Medicated For All Mouth Sores, Gel

Benzocaine 20%

Menthol 0.1%

Zinc Chloride 0.15%

Oral pain reliever and Oral astringent

Use

for the temporary relief of pain associated with 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

- more than directed
- for more than 7 days unless directed by a dentist or doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

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

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 to affected area up to 4 times daily or as directed by a dentist or doctor

Children between 2 and 12 years of age	Ask a doctor before use. Should be supervised in the use of this product
Children under 2 years of age	Do not use

Other information

do not use if Tamper-Evident Tab is open before first use

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

Questions or comments?

call us at 1-800-952-5080 M-F 9am-5pm ET or visit our website at **www.orajel.com**

#1 ORAL PAIN

RELIEF BRAND

FOR ADULTS

EXTRA STRENGTH

Orajel™

3X MOUTH SORES

MEDICATED

IMMEDIATE PAIN RELIEF

ORAL PAIN

RELIEVER/

ASTRINGENT

Provides

Long-Lasting

Pain Relief*

Helps Protect Sores

from Irritation

Delivers Targeted

Pain Relief

GEL

NET WT

0.18 OZ (5.1 g)

ORAJEL 3X MEDICATED FOR ALL MOUTH SORES

benzocaine, menthol, zinc chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-783
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
POVIDONE (UNII: FZ989GH94E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBIC ACID (UNII: X045WJ989B)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-783-18	1 in 1 PACKAGE	11/01/2019	
1		1.8 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10237-783-42	1 in 1 PACKAGE	11/01/2019	
2		4.2 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:10237-783-12	1 in 1 PACKAGE	11/01/2019	
3		3.5 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	part348	11/01/2019	

Labeler - Church & Dwight Co., Inc. (001211952)

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	manufacture(10237-783)

Revised: 1/2022

Church & Dwight Co., Inc.