

ORAJEL GUM PAIN 3X MEDICATED- benzocaine, menthol, zinc chloride gel
Church & Dwight Co., Inc.

Orajel Gum Pain 3X Medicated, Gel

Active ingredients

Benzocaine 20%

Menthol 0.26%

Zinc chloride 0.15%

Purpose

Oral pain reliever and Oral astringent

Use

for the temporary relief of pain due to minor irritation or injury of the mouth and gums

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

Do not use

- 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

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

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 older

- 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

Inactive ingredients

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, water

Questions or comments?

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

Principal Display Panel

#1 ORAL PAIN

RELIEVER BRAND

FOR ADULTS

Open Tube Tip

Orajel

GUM PAIN

3X MEDICATED GEL

INSTANT PAIN RELIEF

20% Benzocaine to Relieve Gum Pain

Cooling Relief to Soothe Gums

Relieves Gum Irritation

ORAL PAIN RELIEVER/ASTRINGENT

NET WT

0.125oz (3.5g)



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GUM PAIN 3X MEDICATED

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Orajel

TAMPER-EVIDENT TAB

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TAMPER-EVIDENT TAB

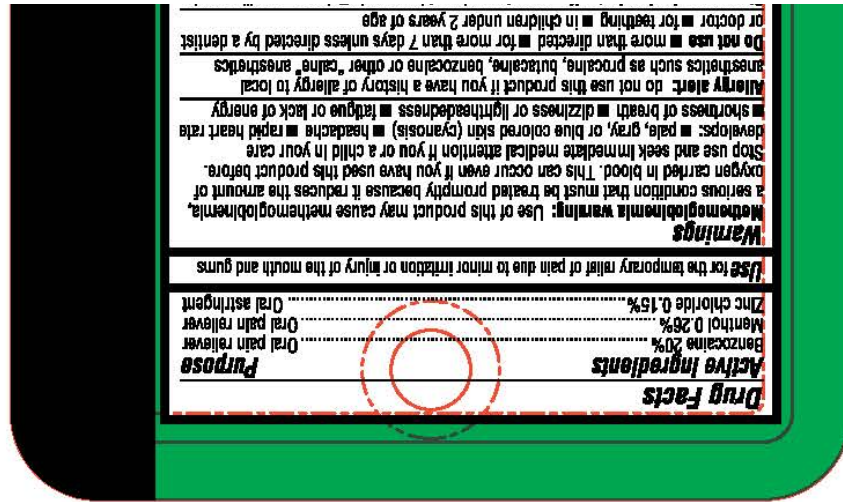
Church & Dwight Co., Inc.
 Englewood, NJ 07620 USA
 ORAJEL is a trademark of Church & Dwight Co., Inc.
 The maker of the Orajel™ brand does not manufacture store brand anal pain products.
 DJFC-00500-01 72016656



Directions
 Stop use and ask a doctor if ■ symptoms do not improve in 7 days ■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens
 Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.
 Adults and children 2 years of age and over 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
Inactive ingredients ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, water
Questions or comments? call us at 1-800-952-5050 M-F 9am-5pm ET or visit our website at www.orajel.com

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ORAJEL GUM PAIN 3X MEDICATED

benzocaine, menthol, zinc chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-792
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
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-792-12	1 in 1 PACKAGE	12/17/2019	

1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10237-792-42	1 in 1 CARTON	12/17/2019	
2		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 DRUG	M022	12/17/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	MANUFACTURE(10237-792)

Revised: 1/2023

Church & Dwight Co., Inc.