

ORAJEL GUM PAIN 3X MEDICATED- 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 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)



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 | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 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.