

PROJEL-20- benzocaine gel
Septodont, 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.

Projel-20 Mint

Active Ingredient:

Benzocaine 20%

Inactive ingredients:

Flavor, polyethylene glycol, sodium saccharin

Purpose:

Oral Anesthetic intended for adults and children 2 years of age and older.

Use:

Projel-20[®] is a 20% benzocaine topical anesthetic gel packaged in 60 gram jars for use in the operatory. The gel is indicated for temporary relief of pain associated with minor irritation or injury in the mouth and gums or of pain due to canker sores, denture sores or orthodontic appliances. ProJel-20[®] is available in four flavors: Cherry, Pina Colada, Bubblegum and Mint.

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 on patients with history of allergy due to local anesthetics such as procaine, butacaine, benzocaine or other “caine” anesthetics.

DO NOT USE

- For more than 7 days unless directed by a dentist or physician
- If you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other ‘caine’ anesthetics
- **For teething**
- **In children under 2 years of age**

WHEN USING THIS PRODUCT

- Do not exceed recommended dosage
- Patient should not ingest or swallow
- Avoid contact with eyes
- Localized allergic reactions may occur after prolonged or repeated use
- Discontinue use if irritation/inflammation or fever and infection develops

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.

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

If more than used for pain relief is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions:

Apply only amount needed to the oral mucosa to prevent or relieve pain.
Children under 2 years of age: do not use.

OTHER INFORMATION

For professional use only in the practice of dentistry.
Store at 20°C - 25°C (68°F - 77°F). Do not permit to freeze.

HOW SUPPLIED

Projel-20[®], Benzocaine 20% is available in in 60 gram jars (NDC 0362-0123-05).

Manufactured by:
SEPTODONT, Inc.
416 S. Taylor Ave
Louisville, CO 80027
800-872-8305 |
www.septodontusa.com

Rev. 10/2018

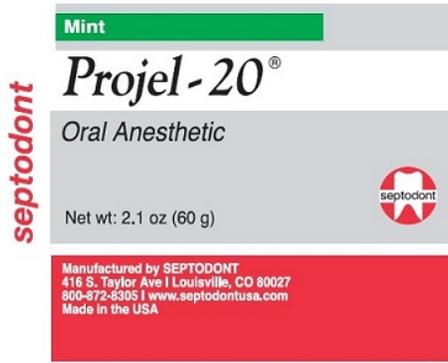
Mint Projel Label

Storage: 20° - 25°C (68° - 77°F)

Active ingredient: benzocaine 20%
Inactive ingredients: flavor, polyethylene glycol, sodium saccharin.

*For professional use only
in the practice of dentistry*

03 82 Projel 30 00
Exp:
Lot:



Do not use if protective seal under cap is broken or damaged.

Indications:

For temporary pain relief of oral mucosa due to minor irritation or injury of the mouth and gums or of pain associated with canker sores, dentures or orthodontic appliances. For topical application to oral mucosa only.

Warnings: PATIENT SHOULD NOT INGEST OR SWALLOW.

AVOID CONTACT WITH EYES. Localized allergic reactions may occur after prolonged or repeated use. Do not use on patients with history of allergy due to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. Discontinue use if irritation-inflammation or fever and infection develops. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

LABP 1807-B

PROJEL-20

benzocaine gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0362-0123 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5) | BENZOCAINE | 20 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) | |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8AQ) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0362-0123-05 | 60 g in 1 JAR; Type 0: Not a Combination Product | 12/15/1989 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 12/15/1989 | 08/30/2020 |

Labeler - Septodont, Inc. (627058738)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|---|
| Septodont Inc. | | 012925513 | manufacture(0362-0123) , label(0362-0123) |

