BENZO-JEL- benzocaine gel Henry Schein 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.

Active Ingredients

Benzocaine 200 mg (in each g)

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

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 the 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 a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Do not use

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a physician before use.

Keep Out of Reach of Children.

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

Store at 59°-86°F (15-30°C). Protect from freezing.

Inactive Ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

Questions or Comments?

1-800-472-4346

Distributed by (in US only): HENRY SCHEIN INC. 135 DURYEA ROAD MELVILLE, NY 11747 USA HENRY SCHEIN®

For Professional Use Only

Made in USA

20% Benzocaine

BENZO-JEL® Topical Anesthetic Gel

1 FL. 0Z. (29.6 mL)

| Urug Facts Active inaredients | |
|---|--|
| Benzocaine 200 mg <i>(in each g)</i> | directed by a physician. If sore |
| Purpose Oral Anesthetic | moutn symptoms ao not improve in 7 days; irritation, pain, or |
| Use | redness persists or worsens; or |
| For oral mucosal use only, as | if swelling, rash or fever develops, |
| directed by dentist. For the temporary relief of pain due | For teething |
| to minor dental procedures. | • in children under 2 years of age |
| Warnings | When using this product Avoid contact with evec If |
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| may cause methemoglobinemia, | Do not exceed recommended |
| a serious condition that must be | dosage. If more than used for |
| treated promptly because it | pain is accidentally swallowed, det medical heln or contact a |
| reduces the amount of oxygen | Poison Control Center right away. |
| occur even if voll have used this | If pregnant or breast feeding, |
| product before. Stop use and | ask a physician before use. |
| seek immediate medical | Neep out of reach of children. |
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| shortness of breath | Other information |
| • dizziness or lightheadedness | Store at 59° - 86° F (15 - 30° C). |
| • laugue of lack of effergy Alleray Alert: Do not lise on | Protect from freezing. |
| patients with a history of | Inactive ingredients |
| allergies to local anesthetics | flavoring, PEG 3350, PEG 400, |
| such as procaine, butacaine, | sodium saccharin, water. May |
| berzocaine or other "caine" | contain blue # I, green #3, green #5 rad #3 rad #78 rad #40 |
| anesthetics. | yellow #5, (tartrazine), yellow #6, |
| • for more than 7 days unless | as a color additive. |
| | Questions or comments? 1-800-477-4346 |
| | 0 |

BENZO-JEL

benzocaine gel

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|-------------------------------|-------------------|--------------------|--|--|---------------|--|--|
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| Product Information | | | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | | | NDC:0404-0032 | | |
| Route of Administration | DENTAL | | | | | | |
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| | | | | | | | |
| Active Ingredient/Active | Molety | | | | | | |
| Ingred | gth | Strength | | | | | |
| BENZOCAINE (UNII: U3RSY48JW5) | | 200 mg in 1 g | | | | | |
| | | | | | | | |
| | | | | | | | |
| Inactive Ingredients | | | | | | | |
| | | Strength | | | | | |
| POLYETHYLENE GLYCOL 3350 (| UNII: G2M7P15E5P) | | | | | | |
| | | | | | | | |
| POLYETHYLENE GLYCOL 400 (U | | | | | | | |

| WATER (UNII: 059QF0 | | | | | | | |
|----------------------------|---------------------------|-----------------------------|--------------|------|-------------------------|-----------------|----------------|
| FD&C BLUE NO. 1 (U | | מי | | | | | |
| D&C GREEN NO. 5 (U | | | | | | | |
| FD&C RED NO. 3 (UN | - | | | | | | |
| D&C RED NO. 28 (UN | | | | | | | |
| FD&C YELLOW NO. 5 | | | | | | | |
| FD&C RED NO. 40 (U | | | | | | | |
| FD&C GREEN NO. 3 (| | | | | | | |
| FD&C YELLOW NO. | 6 (UNII: H77VE | I93A8) | | | | | |
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| | | | | | | | |
| Product Charac | teristics | | | | | | |
| Color | | green | Score | | | | |
| Shape | | | Size | | | | |
| Flavor | | MINT | Imprint Code | | | | |
| Contains | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | ode Package Description | | | Ν | larketing Start Date | Marketiı Dat | |
| | 0 g in 1 JAR; T roduct | ype 0: Not a Combir | nation | 06/0 | 01/2018 | | |
| | | | | | | | |
| Marketing In | formati | on | | | | | |
| Marketing Category | Applicat | ion Number or M Citation | onograph | h | Marketing Start Date | | ing End Ite |
| OTC monograph not final | part356 | | | | 05/01/2016 | | |
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Labeler - Henry Schein Inc. (012430880)

Revised: 1/2022

Henry Schein Inc.