**ORAL PAIN RELIEF- benzocaine and benzalkonium chloride gel**
**Universal Distribution Center LLC**

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**Oral Pain Relief Gel**

***Active Ingredients***

Benzocaine 20%

Benzalkonium Chloride 0.1%

***Purpose***

Oral pain reliever

Antiseptic

***Use***

■ for the temporary relief of pain due to toothaches

■ to help protect against infection in minor oral irritation

***Warnings***

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduce 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 lightheadness
• 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 or other "caine" anesthetics

**Do not use**

■ more than directed

■ for more than 7 days unless directed by a physician or healthcare provider

**Stop use and ask a physician if**

■ swelling, rash or fever develops

■ irritation, pain or redness persists or worsens

■ symptoms do not improve in 7 days

**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 over: apply a small amount of the product to the cavity and around the gum surrounding the teeth Use up to 4 times daily or as directed by a physician or healthcare provider

■ children under 12 years of age: should be supervised in the use of this product

■ children under 2 years of age: Do not use

***Other information***

■ this preparation is intended for use in cases ot toothache, only as a temporary expedient until a physican can be consulted

■ do not use continuously

■ avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

■ do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

***Inactive ingredients***

ammonium glycyrrhizate, flavor, polyethylene glycol, sodium saccharin, sorbic acid, purified water, FD&C Yellow#5, FD&C Red#40

**Package Label**

**Oral Pain Relief Gel**

NET WT. 0.5 oz (14 g)


# ORAL PAIN RELIEF

benzocaine and benzalkonium chloride gel

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:52000-060 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BENZOCAINE** (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 0.2 g in 1 g |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.01 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **AMMONIUM GLYCYRRHIZATE** (UNII: 3VRD35U26C) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SORBIC ACID** (UNII: X045WJ989B) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |

| | |
|---|---|
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:52000-060-02 | 1 in 1 CARTON | 05/01/2024 | |
| **1** | | 14 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 | 01/05/2024 | |

## Labeler - Universal Distribution Center LLC (019180459)

## Registrant - Savvy Care And Cosmetics Pvt. Ltd. (915039748)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Savvy Care & Cosmetics Pvt. Ltd. | | 915039748 | manufacture(52000-060) |

Revised: 5/2024 Universal Distribution Center LLC