**LUZEN WHITENING GEL- hydrogen peroxide gel**
**BIOSTECH CO., LTD.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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hyeroge peroxide

for external use only

oral debriding

Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

water, glycerin, peg400, ethanol, pvp k29/32(povidone), pvp k90(povidone), aerosil 200, flavor, etc

Keep out of children

for external use only

keep out of reach children

## Drug Facts

**Active Ingredient** **Purpose**
**Hydrogen Peroxide 2.80%(W/W).....Oral Debriding**

### Uses
Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

### Directions
Use up to 2 times daily after meals and at bedtime
children under 13 years of age Do not use

### Warnings
For external use only

### Keep out of reach of children.
If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

### Stop use and ask a doctor if
The condition persists or gets worse
Sore mouth symptoms do not improve in 7 days
Irritation, pain or redness persists or worsens
Swelling, rash or fever develops

### Other Information
Keep tightly closed and in a dark place at room temperature

### Inactive Ingredients
*Water, , Glycerine, PEG400, Ethanol, PVP K29/32(Povidone), PVP K90(Povidone), Aerosil 200, Flavor(Applemint HF62184), Citric Acid, Sodium Citric Acid, Polysorbate 80, Xylitol, Erythritol, Sucralose*

### Questions or Comments?

# LUZEN WHITENING GEL
hydrogen peroxide gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70812-010 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 2.8 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

| | |
|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **XYLITOL** (UNII: VCQ006KQ1E) | |
| **ERYTHRITOL** (UNII: RA96B954X6) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70812-010-01 | 4 g in 1 BOTTLE; Type 0: Not a Combination Product | 12/23/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 12/23/2020 | |

## Labeler - BIOSTECH CO., LTD. (687294330)

## Registrant - BIOSTECH CO., LTD. (687294330)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| BIOSTECH CO., LTD. | | 687294330 | manufacture(70812-010) |

Revised: 12/2020 BIOSTECH CO., LTD.