

FOAMGLE FOAM MOUTHWASH SUPER MINT- allantoin liquid KMPHARMACEUTICAL 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](#).

Active ingredient(s)

Allantoin 0.05%

Purpose

Oral Tissue protectant, alleviation of oral irritation

Use(s)

- Aids in the prevention of dental cavities.
- Helps remove plaque that leads to gingivitis, an early form of gum disease.
- Helps protect the mouth against everyday irritants
- Freshens breath while protecting oral tissues
- Helps soothe and protect irritated gums and mouth

Warnings

- For oral use only; do not swallow.
- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- 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 dentist if • Gingivitis, bleeding, or redness persists for more than 2 weeks. • You have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.
- If pregnant or breast-feeding, ask a health professional before use.

Directions

- Dispense foam directly into mouth • Swish thoroughly for 30 seconds to 1 minute, and then spit out. Do not swallow the rinse • Use 2–3 times daily or as directed by a dentist or doctor.

Other Information

- Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light
- Store at 15°–30°C (59°–86°F)
- Do not freeze.

Questions

Inactive ingredients

Water, Glycerin, Xylitol, Steviol glucoside, Sodium Lauryl Sulfate, Sodium Bicarbonate, Methylparaben, Polyoxyl 40 Hydrogenated Caster Oil, Flavor, Menthol, Glycyrrhiza Uralensis (Licorice) Extract, Punica Granatum Fruit Extract, Rosmarinus Officinalis (Rosemary) Extract, Chamomilla Recutita (Matricaria) Extract, Propolis Extract, Camellia Sinensis (Green Tea) Leaf Extract

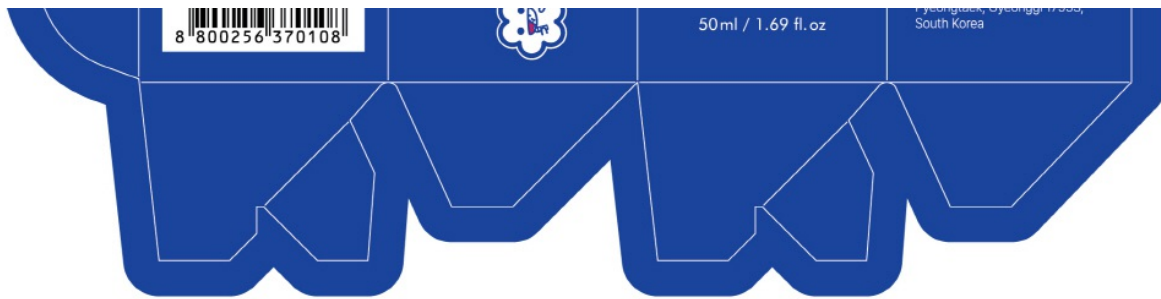
Foamgle Mouthwash – Super Mint

37mm

37mm

37 x 37 x 130 mm





FOAMGLE FOAM MOUTHWASH SUPER MINT

allantoin liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50555-210 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 0.05 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| PEG-40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50555-210-02 | 1 in 1 CARTON | 05/01/2025 | |
| 1 | NDC:50555-210-01 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| unapproved drug | | 05/01/2025 | |

| | | | |
|-------|--|------------|--|
| other | | 05/01/2025 | |
|-------|--|------------|--|

Labeler - KMPHARMACEUTICAL CO.,LTD (689850153)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| KMPHARMACEUTICAL Co.,Ltd. | | 689850153 | manufacture(50555-210) |

Revised: 5/2025

KMPHARMACEUTICAL CO.,LTD