# KARL AND HANS BOTANIC JASMINE- sodium monofluorophosphate paste, dentifrice PIGEON CORPORATION

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.

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### **Drug Facts**

### **ACTIVE INGREDIENT**

Sodium Monofluorophosphate 0.74%

### **INACTIVE INGREDIENT**

D-Sorbitol Solution, Concentrated Glycerin, Water, Silicon Dioxide, Sodium Lauryl Sulfate, Jasmine Flavor, Xylitol, Sodium Carboxymethylcellulose, Enzymatically Modified Stevia, Jasmine Mint Flavor, Titanium Oxide, Spearmint Oil, Aluminium Chlorohydroxy Allantoinate, Hydroxyapatite, L-Menthol, Propolis Extract10, Matricaria Extract, Green Tea Extract, Aloe Extract, Rosemary Extract, Grapefruit Extract, Taraxacum, officinale Extract, Clove extract, Moutan Root Extract

### **PURPOSE**

Caries prevention

### WARNINGS

- Contains 977ppm of fluoride.
- Do not swallow and rinse mouth thoroughly after use
- If you experience any problems with your gums or mouth during use, discontinue use and consult your doctor.
- For children under 6 years of age, use small amounts of toothpaste. And use it under the supervision of a guardian to avoid sucking or swallowing.
- Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities.
- Keep out of the reach of children under 6 years of age.

### **KEEP OUT OF REACH OF CHILDREN**

■ Keep out of the reach of children under 6 years of age.

### Uses

- Keep your mouth clean.
- Prevents tooth decay caused by fluoride and removes bad breath.

- Increases aesthetic effect.
- Prevention of plaque deposition, removal of plaque (anti-prag)

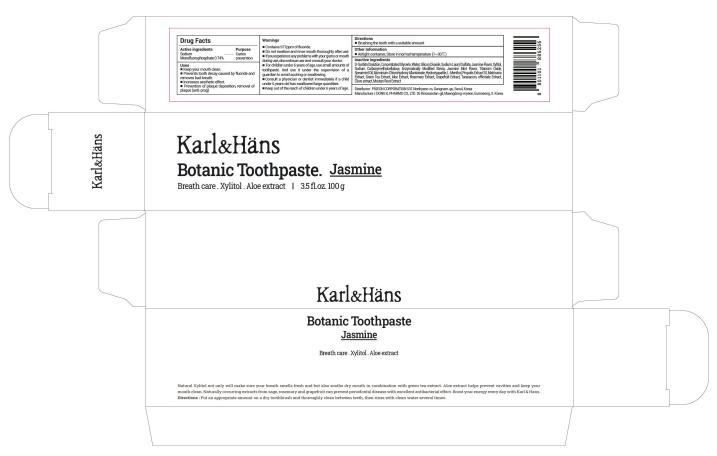
### **Directions**

■ Brushing the teeth with a suitable amount

### Other information

 $\blacksquare$  Airtight container, Store in normal temperature (1~30°C)

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



# KARL AND HANS BOTANIC JASMINE sodium monofluorophosphate paste, dentifrice Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:78151-020 Route of Administration TOPICAL Active Ingredient/Active Moiety Basis of Administration HUMAN OTC DRUG Item Code (Source) NDC:78151-020

| інугеціені маше   | Strength     | Strength           |
|---|--------------|--------------------|
| <b>Sodium Monofluorophosphate</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.74 g<br>in 100 g |

| Inactive Ingredients        |          |  |
|-----------------------------|----------|--|
| Ingredient Name             | Strength |  |
| SORBITOL (UNII: 506T60A25R) |          |  |
| Glycerin (UNII: PDC6A3C0OX) |          |  |
| Water (UNII: 059QF0KO0R)    |          |  |

| Packaging      |  |                         |                       |  |
|----------------|--|-------------------------|-----------------------|--|
| # Item Code    | Package Description                                | Marketing Start<br>Date | Marketing End<br>Date |  |
| NDC:78151-020- | 1 in 1 CARTON                                      | 05/01/2022              |                       |  |
| NDC:78151-020- | 100 g in 1 TUBE; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part355                                     | 05/01/2022              |                       |
|                       |   |                         |                       |

# Labeler - PIGEON CORPORATION (687877613)

## Registrant - PIGEON CORPORATION (687877613)

| Establishment            |         |           |                            |  |
|--------------------------|---------|-----------|----------------------------|--|
| Name                     | Address | ID/FEI    | <b>Business Operations</b> |  |
| DONG IL PHARMS CO., LTD. |         | 557810721 | manufacture(78151-020)     |  |

Revised: 5/2022 PIGEON CORPORATION