

**KARL AND HANS BOTANIC DOUBLE MINT- 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.

Drug Facts

ACTIVE INGREDIENT

Sodium Monofluorophosphate 0.74%

INACTIVE INGREDIENT

D-Sorbitol Solution, Concentrated Glycerin, Water, Silicon Dioxide, Sodium Lauryl Sulfate, Xylitol, Double Mint Flavor, Sodium Carboxymethylcellulose, Sodium Chloride, Double Mint Flavor, Titanium Oxide, Peppermint Oil, Aluminium Chlorohydroxy Allantoinate, Enzymatically Modified Stevia, Hydroxyapatite, L-Menthol, Propolis Extract¹⁰, Matricaria Extract, Green Tea Extract, Aloe Extract, Rosemary Extract, Grapefruit Extract, Houttuynia Cordata Extract, Sage 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)

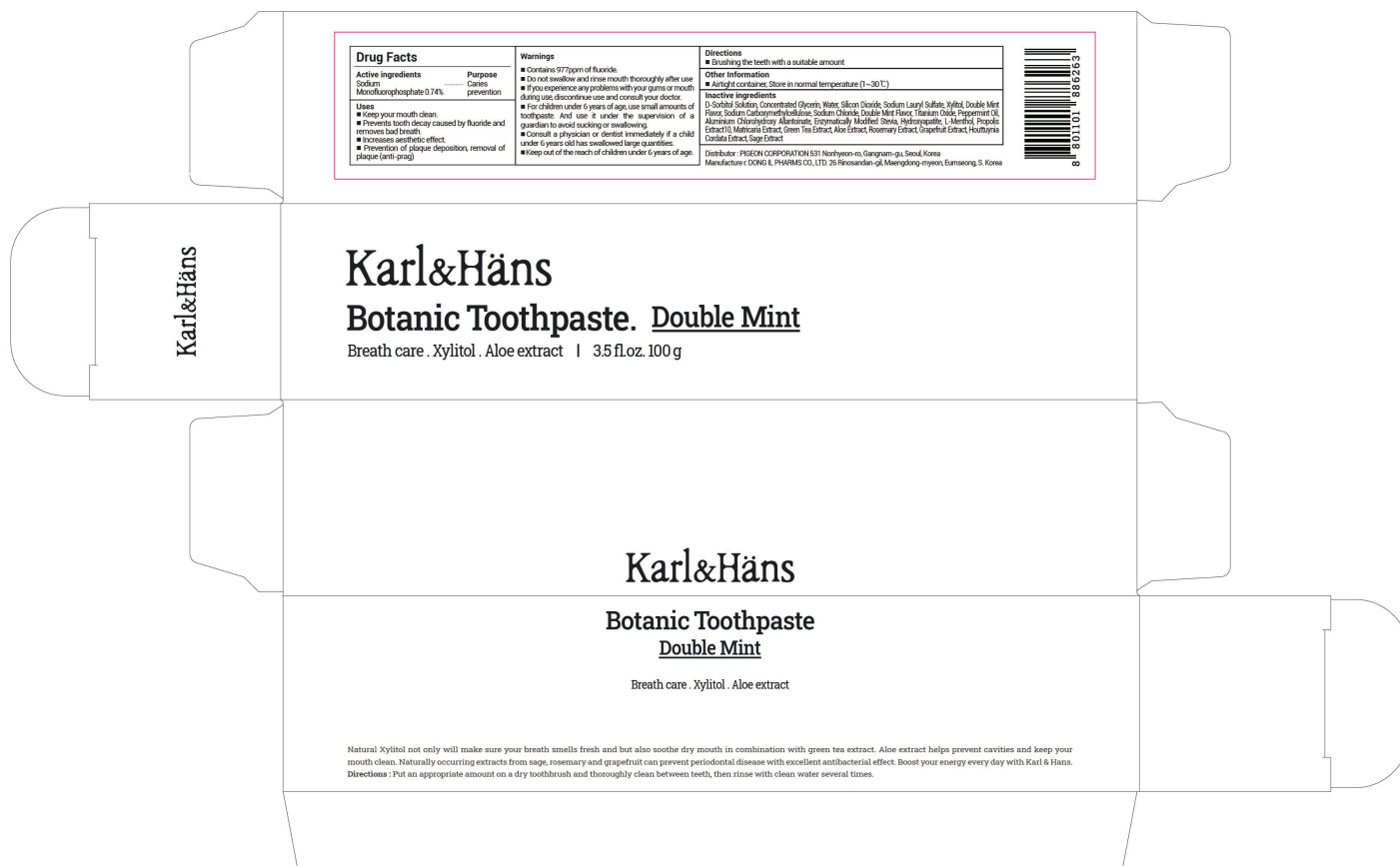
Directions

- Brushing the teeth with a suitable amount

Other information

- Airtight container, Store in normal temperature (1~30°C)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



KARL AND HANS BOTANIC DOUBLE MINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78151-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
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Ingredient Name		Strength	Strength	
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.74 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
Sorbitol (UNII: 506T60A25R)				
Glycerin (UNII: PDC6A3C00X)				
Water (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78151-030-02	1 in 1 CARTON	05/01/2022	
1	NDC:78151-030-01	100 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 final	part355	05/01/2022		

Labeler - PIGEON CORPORATION (687877613)

Registrant - PIGEON CORPORATION (687877613)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO., LTD.		557810721	manufacture(78151-030)

Revised: 5/2022

PIGEON CORPORATION