THE GARGLE - sodium fluoride mouthwash PBS Co., Ltd.

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

sodium fluoride

purified water, ethyl alcohol, allantoin, glycerin, xylitol, sodium saccharin, green tea, malic acid, lactic acid, sodium benzoate, citric acid peg-40 hydrogenated castor oil, sodium citrate, l-menthol, red ginseng ext, ulmus ext, red ginseng fragrance, mint fragrance, houttuynia ext, propolis ext

for dental care

keep out of reach of the children

☐ Turn the container cap and open, pour The Gargle into the cap about 10-15ml (not to overflow the cap) and

put into mouth.

□ Goggle it thoroughly all over the inner mouth about 10 seconds.

☐ After ☐, in order to sterilize mouth, hold the liquid in the mouth about 30 seconds and spit out

do not swallow

for oral administration

가글위의 가글 - 더가글!

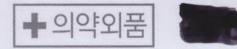
특허성분함유

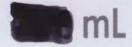
Bard Salvasard Houttuynia Estract • Houttuynia Estr



The gargle is an oral care product composed of oriental medicine extracts showing outstanding prevention effects on tooth decay







THE GARGLE

sodium fluoride mouthwash

P	ro	duct	Intormation
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HUMAN OTC DRUG NDC:41525-7001 Product Type Item Code (Source)

Route of Administration DENTAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8 ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.02 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALLANTO IN (UNII: 344S277G0Z)		
XYLITOL (UNII: VCQ006KQ1E)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		

Packaging				
# Item	Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41525-	7001-1	600 mL in 1 BOTTLE		
2 NDC:41525-	-7001-2	780 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	0 1/22/20 15		

Labeler - PBS Co., Ltd. (690329669)

Registrant - PBS Co., Ltd. (690329669)

Establishment				
Name	Address	ID/FEI	Business Operations	
PBS Co., Ltd.		690329669	manufacture(41525-7001)	

Revised: 1/2015 PBS Co., Ltd.