DENTAL PRO - 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, caramel color

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

DENTAL PRO

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41525-6001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41525-6001-1	250 mL in 1 BOTTLE		
2	NDC:41525-6001-2	600 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/11/2014	

Labeler - PBS Co., Ltd. (690329669)

Registrant - PBS Co., Ltd. (690329669)

Establishment

Name	Address	ID/FEI	Business Operations
PBS Co., Ltd.		690329669	manufacture(41525-6001)

Revised: 9/2014 PBS Co., Ltd.