DR. DENTAL CARE- allantoin, sodium fluoride liquid
JANGIN PHARM 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.

Active ingredient : Sodium fluoride

Preservative : Sodium Benzoate

Additives : Allantoin, Glycerin, Xylitol, Citric Acid Hydrate, Sodium Citrate Hydrate, Caramel Colorant, camellia sinensis catechins, L-Menthol, Sophora Angustifolia Root Extract, Glycyrrhiza Inflata Root Extract, Red Ginseng Extract, Saccharin Sodium Hydrate, DI-Water

It keeps your teeth white, strong, and clean your mouth. It makes your mouth feel fresh, prevent cavities, and remove bad breath. Increase the aesthetic effect. Prevent gingivitis, periodontitis (pyorrhoea alveolaris), periodontal disease, and gum disease.

Keep out of reach of children

● Administration and doses : Hold a suitable amount (10~15ml) in your mouth for about 30 seconds, then spit it out, and brush your teeth with a brush.

● Caution : 1) The fluoride content of toothpaste is 90.5 ppm. 2) Take care not to swallow, and rinse your mouth thoroughly after use. 3) If gum or mouth damage is caused by using this toothpaste, stop using it and consult a doctor or dentist. 4) If used by children under the age of six years, use small amount of toothpaste about the size of peas at a time. Use under supervision of a guardian to avoid sucking or swallowing. 5) If a child under 6 years old swallows a large amount, consult a physician or dentist immediately. 6) Keep out of the reach of children under 6 years old. 7) This medicine contains sodium benzoate which can cause slight irritation to the skin, eyes and mucous membrane. 8) To prevent misuse and preserve quality, do not change the container. 9) This product contains fluoride requires guidance from parents or adults when used by children.

For dental use only

DR. DENTAL CARE

allantoin, sodium fluoride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69255-300
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69255-300-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/01/2018	

Labeler - JANGIN PHARM CO.,LTD. (688733680)

Registrant - JANGIN PHARM CO.,LTD. (688733680)

Establishment

Name	Address	ID/FEI	Business Operations
JANGIN PHARM CO.,LTD.		688733680	manufacture(69255-300)

Revised: 1/2019 JANGIN PHARM CO.,LTD.