

DR DENTAL CARE 250ML- 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

Active ingredient:
Sodium fluoride 0.02% (0.009% w/v fluoride ion)

INACTIVE INGREDIENT

Inactive ingredients:
Water, Alcohol (3%), Xylitol, Glycerin, Allantoin, Citric Acid, Sodium Citrate, Catechins, Sodium Benzoate, Menthol, Red Ginseng, Sophora Angustifolia Root, Swertia, Licorice, Caramel

PURPOSE

Purpose: Anticavity

WARNINGS

Warning:
1. Keep out of reach of children under 6 years old.
2. Avoid direct sunlight, store in room temperature.
3. Close lid after use.
4. Consult doctor before use if you are allergic to any of the ingredients.
5. If significant amount is accidentally swallowed, drink large amount of milk and get medical help.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:
If significant amount is accidentally swallowed, drink large amount of milk and get medical help.

Use

Use:
Mouthwash with outstanding oral disease prevention effect

Directions

Directions:
Rinse mouth with 10-15ml for 30 seconds.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



DR DENTAL CARE 250ML

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69255-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 mg in 250 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69255-020-01	250 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/01/2014	

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(69255-020)

Revised: 9/2014

Jangin Pharm Co., Ltd.