# DR. ZENNI NATURAL WHITETOOTHPASTE- sodium monofluorophosphate paste, dentifrice Zeniton 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.

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#### **ACTIVE INGREDIENT**

Sodium Monofluorophosphate 0.75%

#### **PURPOSE**

Anticavity

#### **KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children

#### Uses

- Helps protect against cavities
- Removal of plaque

#### WARNINGS

Keep out or reach of children under 6 yrs. of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

#### **INACTIVE INGREDIENTS**

D-Sorbitol Solution, Precipitated Calcium Carbonate, Water, Hydroxyapatite, Concentrated Glycerin, Sodium Cocoyl Glutamate, Xanthangum, Xylitol, Lime Flavor, Apple Mint Flavor, Grapefruit Seed Extract, Peppermint Oil, Sodium Chloride, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Tocopherol Acetate, Green Tea Extract

#### **Directions**

- Adults and children 2 years of age and older: Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or doctor.
- Children under 6 years: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
- Children under 2 years: Consult a dentist or doctor.

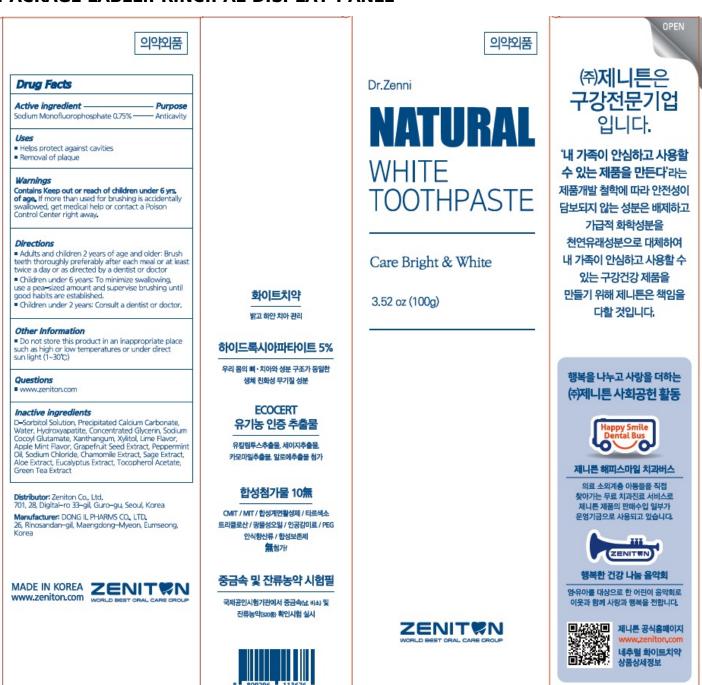
#### Other Information

■ Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light  $(1\sim30^{\circ}C)$ 

#### **QUESTIONS**

www.zeniton.com

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



sodium monofluorophosphate paste, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73029-0013

**Route of Administration** DENTAL

## **Active Ingredient/Active Moiety**

Active ingredient/Active Molety		
Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.7581 g in 100 g

## Inactive Ingredients Ingredient Name Strength

XYLITOL (UNII: VCQ006KQ1E)
WATER (UNII: 059QF0KO0R)

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73029- 0013-1	100 g in 1 TUBE; Type 0: Not a Combination Product	11/22/2020	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part355	11/22/2020				

## Labeler - Zeniton Co.,Ltd. (688416831)

### Registrant - Zeniton Co.,Ltd. (688416831)

Establishment				
Name	Address	ID/FEI	Business Operations	
DONG IL PHARMS CO., LTD.		557810721	manufacture(73029-0013)	

Revised: 12/2021 Zeniton Co.,Ltd.