DR. ZENNI NATURAL ORTHODONTICTOOTHPASTE- 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.

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, Water, Silicon Dioxide, Concentrated Glycerin, Hydroxyapatite, Sodium Cocoyl Glutamate, Xanthangum, Red Wine Flavor, Xylitol, L-Menthol, Peppermint Oil, Aminocaproic Acid, Aluminum Chlorohydroxy Allantoinate, Grapefruit Seed Extract, Green Tea Extract, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Sodium Chloride, Tocopherol Acetate

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.

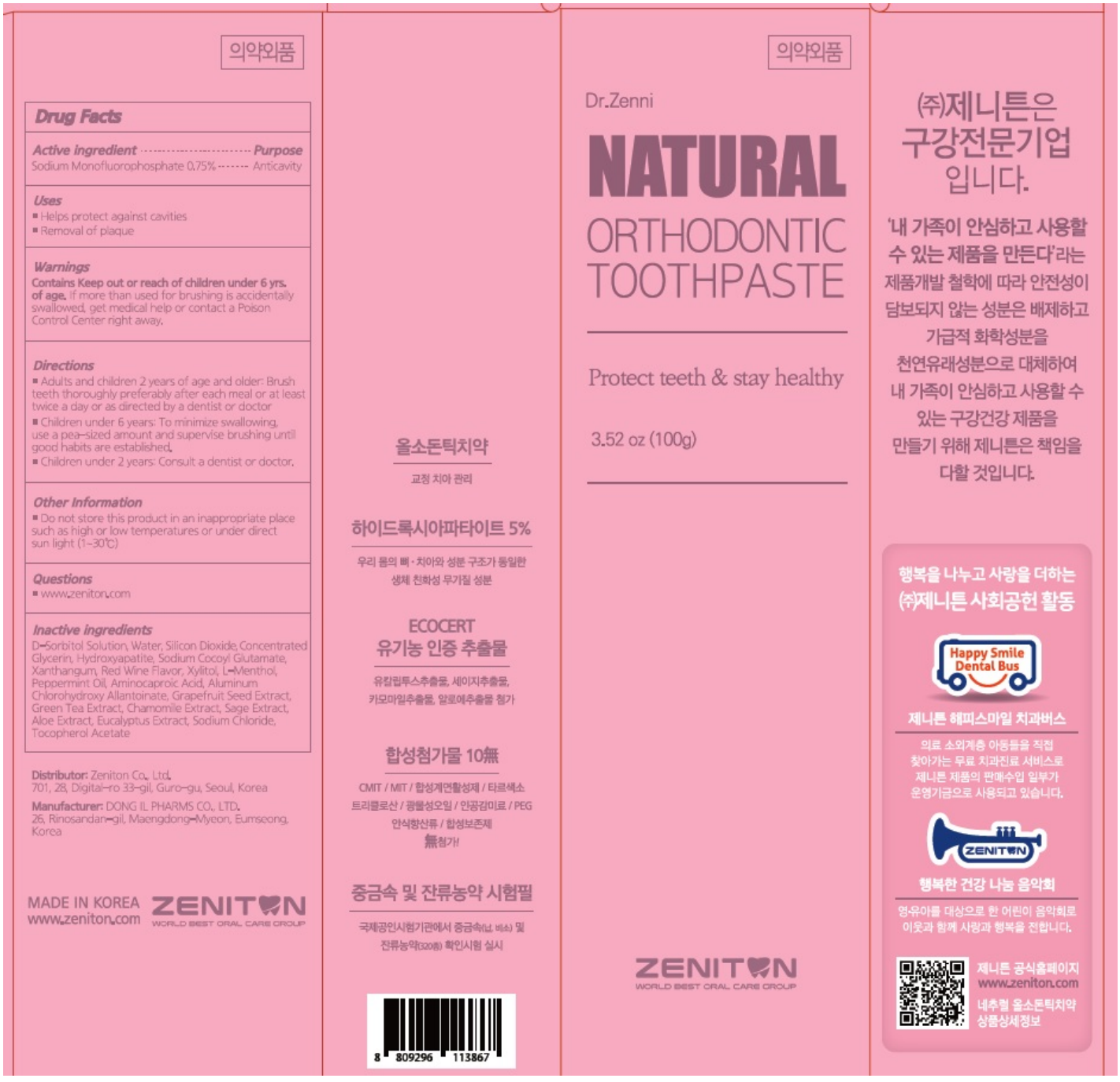
Other Information

■ Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light (1~30℃)

Questions

■ www.zeniton.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73029-0012
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (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:73029-0012-1	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(73029-0012)

Revised: 12/2021 Zeniton Co.,Ltd.