

**ESOPINIO TOPAZ PHYTO- sodium monofluorophosphate paste, dentifrice
ZION SYNTHETIC FIBER 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 Monofluorophosphate 0.76%

INACTIVE INGREDIENT

Inactive Ingredients:

Dicalcium Phosphodihydrate, Tocopheryl Acetate, Sodium Benzoate, d-Sorbitol, Sodium, Carboxymethylcellulose, Silica, Monosodium Phosphate, Sodium Lauryl Sulfate, Sorbitan, Monooleate, Tetrasodium Phyrophosphate, Sodium Saccharin, Xylitol, Mentha (peppermint) Leaf Extract, Fragrance, Salvia Officinalis (Sage) Leaf Extract, Commiphora Myrrha Extract, Cardamom Extract, Chamomilla Recutita (Matricaria) Flower Extract, Blue 1, Yellow 5, Titanium Dioxide, Composite Topaz (MM-1), Water

PURPOSE

Purpose:

1. Cavity Protection
2. Anti-plaque
3. Whitens Teeth
4. Breath Freshening

WARNINGS

Warnings:

If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately. Children under 2 years, ask a dentist or physician.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children under 6 years of age.

INDICATIONS AND USAGE

Indications and usage:

1. Brush teeth thoroughly, preferably after each meal, or at least twice a day,
2. Keep the lid tightly closed after using.
3. Keep at a room temperature

DOSAGE AND ADMINISTRATION

Dosage and Administration:

1. Children 2 to 6 years of age: To minimize swallowing, use only a pea sized amount and supervise child's brushing until good habits are established.
2. Children under 2 years: Ask your dentist or physician.

3. Adults and children 2 years and older: Brush teeth thoroughly, preferably after each meal, or at least twice a day.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



ESOPINIO TOPAZ PHYTO			
sodium monofluorophosphate paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4478 1-230
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Sodium Monofluorophosphate (UNII: C8 10JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408 O)	FLUORIDE ION	0.91 g in 120 g
Inactive Ingredients			
	Ingredient Name		Strength
	Sodium Benzoate (UNII: OJ245FE5EU)		
	Titanium Dioxide (UNII: 15FIX9V2JP)		
	Water (UNII: 059QF0KO0R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44781-230-01	120 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2013	

Labeler - ZION SYNTHETIC FIBER CO., LTD. (688011147)

Registrant - ZION SYNTHETIC FIBER CO., LTD. (688011147)

Establishment

Name	Address	ID/FEI	Business Operations
ZION SYNTHETIC FIBER CO., LTD.		688011147	manufacture(44781-230)

Revised: 8/2013

ZION SYNTHETIC FIBER CO., LTD.