

ZAP APF- sodium fluoride gel
Crosstex International Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredient:

Fluoride Ion 1.23%. A stable thixotropic gel providing 1.23% fluoride ion. Available from 2.09% Sodium Fluoride and Hydrofluoric Acid.

Purpose:

Anticaries Treatment.

Indications and Usage:

This is a prescription fluoride treatment gel used to help prevent dental decay.

- For Professional Use Only. This product is not intended for home or unsupervised consumer use.

Warnings:

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

Dosage and Administration:

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

Other Information:

- Do not store above 25°C/77°F.
- Do not freeze

Inactive Ingredients:

Citric Acid, FD&C Blue #1, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.

Zap
NDC# 24794 101 16
FLUORIDE GEL
Topical Fluoride Ion 1.23% THIXOTROPIC
1 Minute or 4 Minute Treatment
FOR PROFESSIONAL USE ONLY
COTTON CANDY
16 OZ. (454 g)
GLUTEN FREE!
CONTAINS XYLITOL
Patient's Choice[®] Dental Products
from **CROSSTEX**[®]
A CANTEL MEDICAL COMPANY
R_xOnly

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UFGACC-BTL
Rev. 5 - 8/18
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Website: www.crosstex.com E-mail: crosstex@crosstex.com
MADE IN USA

ZAP APF

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:24794-101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)		FLUORIDE ION	5.6 g in 454 g	
Inactive Ingredients				
Ingredient Name		Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Product Characteristics				
Color	blue	Score		
Shape		Size		
Flavor	COTTON CANDY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24794-101-16	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		12/14/2012		

Labeler - Crosstex International Inc. (057728685)