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.

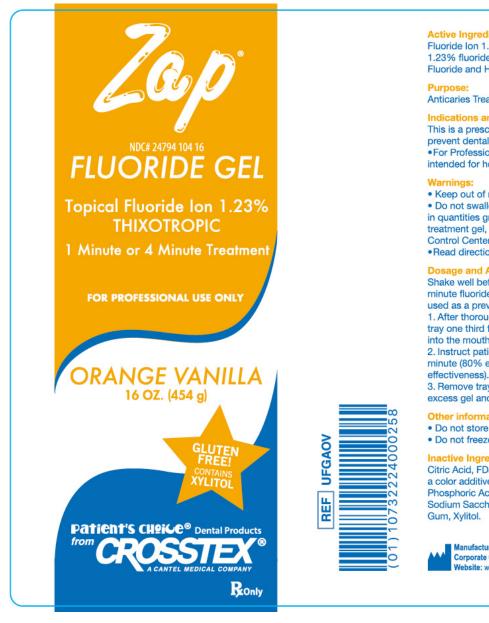
- 1. After thorough prophylaxsis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
- 2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
- 3. Remove trays. Instruct patient 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 Red #40, FD&C Yellow #5 (tartrazine) as a color additive, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.



Active Ingredient:

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

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 preventive 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%
- 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 Red #40, FD&C Yellow #5 (tartrazine) as a color additive, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.

Manufactured for: Crosstex International, Inc. Corporate Office: 10 Ranick Rd., Hauppauge, NY 11788-4209 USA

MADE IN USA

ZAP APF

sodium fluoride gel

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:24794-104 **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 RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	ORANGE, VANILLA	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	

ion Number or Monograph Citation	Marketing Start Date	Marketing End Date
	12/14/2012	
		Citation Date

Labeler - Crosstex International Inc. (057728685)

Revised: 1/2022 Crosstex International Inc.