

PURE SNOW WHITENING- sodium fluoride gel, dentifrice
Itena Clinical

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.

Pure Snow whitening toothpaste

Drug Facts

Active Ingredients

Contains: Sodium Fluoride 0.25%w/w

Purpose

Anticavity

Use

Aids in the prevention of dental decay.

Warnings

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

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.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing.)
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Glycerin, Water (Aqua), Silica, Sorbitol, Xylitol, Flavor (Aroma), Poloxamer 407, Sodium Lauryl Sulfate, Carbomer, FD&C Blue No.1 (CI 42090), FD&C Yellow No.5 (CI 19140), Sodium Benzoate, Sodium Hydroxide, Sparkle (CI 77019, CI 77891), Sucralose, Xanthan Gum

Manufactured For:

ITENA CLINICAL

www.itena-clinical.com

83 Avenue Foch

75116 Paris France

PRINCIPAL DISPLAY PANEL - 28.35 g Tube Label

**PURE
SNOW**

with Fluoride

whitening toothpaste

NET WT 1.0 OZ (28.35g)



- Enlève les colorations et préserve la blancheur.
- Protège la structure dentaire grâce à sa formule faiblement abrasive.
- Laisse une très agréable sensation de fraîcheur.

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Manufactured For:

ITENA CLINICAL
www.itena-clinical.com
83 Avenue Foch
75116 Paris France
Tel.: +33 (0)1 45 91 30 06
Made in USA



- Anticavity, surface stain removing toothpaste.
- A low abrasion formula for maximum enamel and dental work protection.
- Leaves your mouth with a cool, clean, fresh feeling.

Drug Facts (cont.)

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PURE SNOW WHITENING

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52893-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	0.07 g in 28.35 g

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sorbitol (UNII: 506T60A25R)	
Xylitol (UNII: VCQ006KQ1E)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
FD&C Blue No. 1 (UNII: HBR47K3TBD)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52893-001-01	28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	11/30/2012	

Labeler - Itena Clinical (262150858)