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

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.

Drug Facts

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Warnings

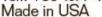
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Manufactured For:

ITENA CLINICAL

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







- 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.)

Directions

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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: PDC6 A3C0 OX)		
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: H3R47K3TBD)		
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			

F	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)

Revised: 11/2012 Itena Clinical