COUNTRY GENT- sodium fluoride powder, dentifrice Heavenly Harvest, Inc.

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.

Drug Facts

Active Ingredient (% by weight)

Sodium Fluoride (0.188%)

Purpose

For Cavity Prevention.

Indication

Aids in prevention of dental decay.

WARNING

KEEP OUT OF REACH OF CHIL-DREN UNDER 6 YRS OF AGE.

If more than used for brushing is swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients

Calcium Carbonate, Sodium Bicarbonate, Peppermint Oil, Stevia Extract.

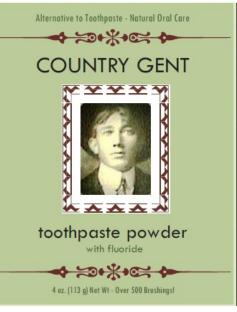
Directions For Use

Adults and Children 6 years of age & older: Apply powder to wet toothbrush; completely cover bristles. Brush 30 seconds. Reapply powder as before and brush again. Rinse and expel thoroughly. Brush teeth, after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Children under 6 years of age: Do not use unless directed by a dentist or doctor.

Package/Label Principal Display Panel





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Country Gent toothpaste powder with fluoride

4 oz. (113 g) Net Wt - over 500 Brushings!

For centuries people used tooth powder as a natural, safe, effective method for tooth care. Our tooth powder cleans teeth and promotes healthy gums by removing plaque.

Gluten Fee, Sulfate Free, Natura Ingredients Produced by Nature with

Minimal Physical Processing. No

Animal Ingredients or Animal Testing.

Also, try Fluoride Free Products.

Naturally Charming, just as a Country Gent Should Be!

Biodegradable Packaging; MADE IN USA by Heavenly Harvest,

Inc., using ingredients and packaging that are

MADE IN USA

countrygentnatural.com

Questions? Call 229.890.3288

Products safe for customers, employees, & the earth's future.

COUNTRY GENT

sodium fluoride powder, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66894-0000
Route of Administration	DENTAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU4080) SODIUM FLUORIDE 1.88 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
STEVIA REBAUDIANA WHO LE (UNII: 6U422Y08O2)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:66894-0000-1	113 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	0 1/0 1/20 12	

Labeler - Heavenly Harvest, Inc. (949907877)

Establishment			
Name	Address	ID/FEI	Business Operations
Heavenly Harvest, Inc.		949907877	LABEL(66894-0000), MANUFACTURE(66894-0000), PACK(66894-0000)

Revised: 2/2012 Heavenly Harvest, Inc.