

**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 CHILDREN 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

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



Gluten Free, Sulfate Free, Natural Ingredients Produced by Nature with Minimal Physical Processing. No

Animal Ingredients or Animal Testing.

Also, try our 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.



Alternative to Toothpaste - Natural Oral Care

COUNTRY GENT



toothpaste powder
with fluoride

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

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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	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		SODIUM FLUORIDE	1.88 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
CALCIUM CARBONATE (UNII: H0G9379FGK)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
STEVIA REBAUDIANA WHOLE (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	01/01/2012		

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.