

CHARCOAL MINT DENTISTRY- sodium fluoride paste
Yangzhou Hongshengding Chemical Co.,Ltd.

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.

71035-903 charcoal MINT dentistry

Active ingredients

Sodium Fluoride 0.24%

Purpose

anticavity

Uses

aids in the prevention of dental cavities.

Warnings

Keep out of the 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.

Keep out of reach of children.

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: Consult a dentist or doctor.

INACTIVE INGREDIENT

HYDRATED SILICA, HYDROXYETHYL
CELLULOSE, WATER, CARBOXYMETHYLCELLULOSE, SACCHARIN SODIUM, SODIUM
PHOSPHATE, TRIBASIC, ANHYDROUS. SODIUM BENZOATE, SODIUM LAURYL
SULFATE, SORBITOL, GLYCERIN

CHARCOAL
WHITENING TOOTHPASTE WITH ACTIVATED CHARCOAL
6 oz

MINT
dentistry

Drug Facts		Drug Facts (continued)	
Active Ingredient Sodium Fluoride (0.24%)	Purpose Anticavity	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.	
Uses Aids in the prevention of dental cavities.		Inactive Ingredients Sorbitol, Aqua, Hydrated Silica, Sodium Lauryl Sulphate, Flavor, Carboxy Methyl Cellulose, Polyethylene Glycol, Sodium Benzoate, Sodium Saccharin, Xanthan Gum, Charcoal Powder, Sodium Pyrophosphate, Menthol, CI28440.	
Warning 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.			

CHARCOAL MINT DENTISTRY

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71035-903
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
HYDROXYETHYL CELLULOSE (40 MPAS AT 2%) (UNII: I2N4ZF9233)	
WATER (UNII: 059QF0K00R)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Product Characteristics				
Color	black	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71035-903-01	72 in 1 CARTON	09/04/2016	
1		1 in 1 BOX		
1		170.1 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71035-903-02	288 in 1 CARTON	09/04/2016	
2		1 in 1 BOX		
2		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	09/04/2016		

Labeler - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)

Registrant - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hongshengding Chemical Co.,Ltd.		543774755	manufacture(71035-903)

Revised: 9/2018

Yangzhou Hongshengding Chemical Co.,Ltd.