WHITE GLO CHARCOAL SENSITIVE- potassium nitrate, sodium monofluorophosphate WHITE GLO USA INC

WHITE GLO CHARCOAL SENSITIVE TOOTHPASTE Kit

Drug Facts

Active ingredients

Potassium nitrate 5%

Sodium monofluorophospahte 0.76% (0.1% w/v fluoride ion)

Purpose

Antihypersensitivity

Anticavity

Uses

• Builds increasing protection against: painful sensitivity of the teeth to cold, heat, acids, sweets or contact. • Aids in the prevention of dental cavities.

Warnings

When using this product,

if irritation occurs discontinue use.

Stop use and ask a dentist if

• the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. • pain/sensitivity still persists after 4 weeks of use.

Keep out of reach of children.

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

Directions

• adults and children 12 years of age and older: • apply at least a 1-inch strip of the product onto a soft bristle toothbrush. • brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing. • Children under 12 years of age:

Consult a dentist or doctor.

Other information

• store below 30°C (86°F)

Inactive ingredients

Sorbitol, hydrated silica, sodium lauryl sulfate, glycerin, water, cellulose gum, chondrus crispus (carrageenan), tetrasodium phosphate, sodium saccharin, sodium benzoate, bamboo charcoal

Questions or comments?

For customer enquiries, please contact: customer.enquiry@whiteglo.com White Glo USA INC. 25 Suffolk Court, Hauppauge, NY, 11788 USA. www.whiteglo.com

Package Labeling:



WHITE GLO CHARCOAL SENSITIVE

potassium nitrate, sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73656-011

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:73656-011-00	1 in 1 KIT	03/16/2020	_

Quantity of Parts

Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOX	150 g		

Part 1 of 1

WHITE GLO CHARCOAL SENSITIVE

potassium nitrate, sodium monofluorophosphate paste, dentifrice

Product Information

Item Code (Source)	NDC:73656-012
Route of Administration	DENTAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION 50 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
SORBITOL (UNII: 506T60A25R)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)			
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)			

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73656-012- 00	1 in 1 TUBE			
1		150 g in 1 BOX; Type 0: Not a Combination Product			

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M022	03/16/2020		

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OTC Monograph Drug	M022	03/16/2020	

Labeler - WHITE GLO USA INC (117345666)

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