

SENSIBLE - sodium lauryl sulfate paste
Guardian Angel of Preventive Dentistry

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

sodium lauryl sulfate

water, glycerin, allantoin, ethanol, polyoxyethylene hydrogenated castor oil, l-menthol, xylitol, steviol glycoside, citric acid, moutan root bark ext, erythritol, sodium citrate, blue no 1 1/250, ascorbic acid

dental care

keep out of reach of the children

- Adults and children 2 yrs. and older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. Do not swallow
- Children under 6 yrs: To minimize swallowing use a pea-sized amount and supervise brushing until good habits are established
- Children under 2 yrs: Ask a dentist or physician

do not swallow

dental care only

Drug Facts

Product name: Sensible Toothpaste (with toothbrush)

Active ingredients

- allantoin

Uses

- dental care
- anticarious

Direction

- **Adults and children 2 yrs. and older:** Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. Do not swallow
- **Children under 6 yrs:** To minimize swallowing use a pea-sized amount and supervise brushing until good habits are established
- **Children under 2 yrs:** Ask a dentist or physician

Warning

- Do not swallow. In case of accidental ingestion, seek professional assistance.

Other Information

- Keep product out of direct sunlight, high temperature and humidity.
- Keep out of reach of children.
- Any items past the expiration date or damaged in transit can be exchanged where you originally purchased the item.

Inactive Ingredient

water, glycerin, sodium lauryl sulfate, ethanol, polyoxyethylene hydrogenated castor oil, l-menthol, xylitol, steviol glycoside, citric acid, moutan root bark ext, erythritol, sodium citrate, blue no 1 1/250, ascorbic acid

SENSIBLE

sodium lauryl sulfate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69086-1001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J) (LAURYL SULFATE - UNII:DIQ16UC154)	SODIUM LAURYL SULFATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69086-1001-1	0.08 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/11/2014	

Labeler - Guardian Angel of Preventive Dentistry (688150332)

Registrant - Guardian Angel of Preventive Dentistry (688150332)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Angel of Preventive Dentistry		688150332	manufacture(69086-1001)

Revised: 7/2014

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