KIDS KARE - stannous fluoride gel
Zila Therapeutics, 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.

Kids Kare - Dye Free Gel

DRUG FACTS

OTC - ACTIVE INGREDIENT

Stannous fluoride 0.4% w/w (0.13% w/v fluoride ion)

Contains 0.4% Stannous Fluoride in a Stable, Water Free Gel

OTC - PURPOSE

Anticavity

INDICATIONS AND USAGE

USES

- Aids in prevention of dental caries (cavities).
- The combined daily use of a fluoride preventive treatment gel and a fluoride toothpaste can help reduce the incidence of dental cavities.

OTC - KEEP OUT OF REACH OF CHILDREN

PLEASE KEEP OUT OF REACH OF CHILDREN.

WARNINGS

- If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- **Use only under guidance or supervision of a dentist.**

DOSAGE AND ADMINISTRATION

DIRECTIONS:

Adults and Children 6 Years and Older	This is a fluoride preventive treatment gel, not a toothpaste. Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing.
Children 6 to 12	Instruct and supervise brushing and rinsing (to minimize swallowing) until good brushing habits are established.
Children Under 6	Ask a dentist or doctor.

OTHER INFORMATION:

This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dental professional.

INACTIVE INGREDIENT

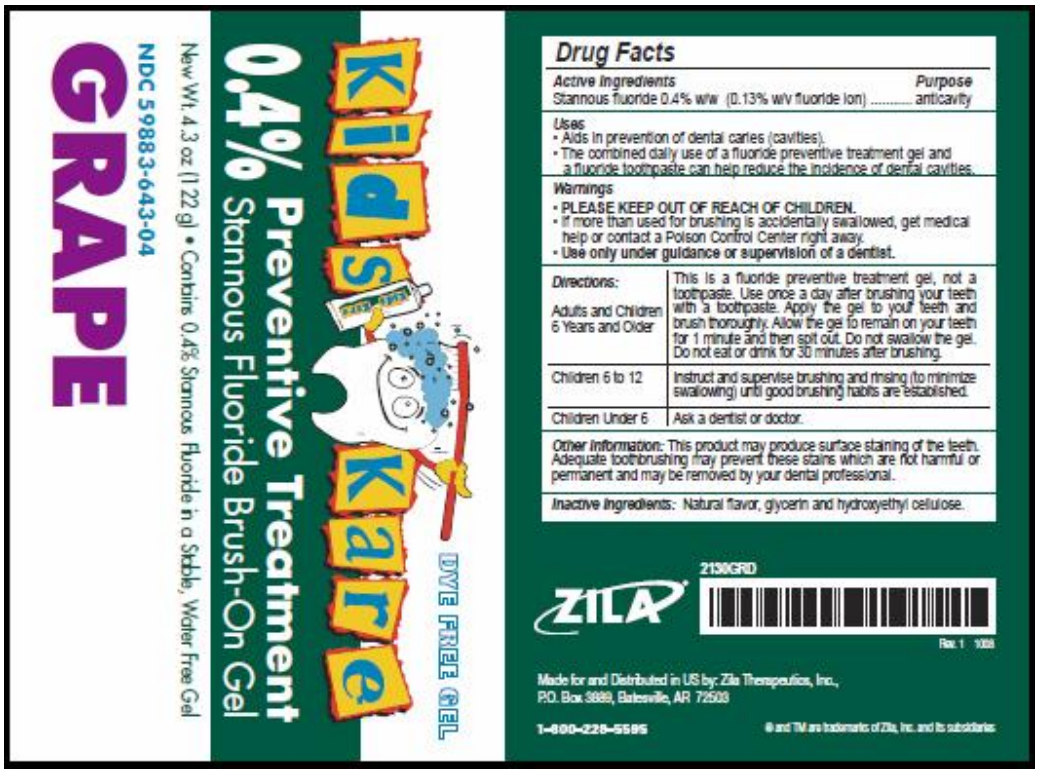
Natural flavor, glycerin and hydroxyethyl cellulose

Made for and Distributed in US by: Zila Therapeutics, Inc.,

P.O. Box 3889, Batesville, AR 72503

1-800-228-5595

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



KIDS KARE

stannous fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:59883-643
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
STANNOUS FLUORIDE (FLUORIDE ION)	FLUORIDE ION	1.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-643-04	122 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/21/2008	

Labeler - Zila Therapeutics, Inc. (883514127)

Establishment

Name	Address	ID/FEI	Business Operations
Zila Therapeutics, Inc.		883514127	MANUFACTURE(59883-643)

Revised: 2/2013 Zila Therapeutics, Inc.