PRO-DEN RX - sodium 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.

Pro-Den Rx

Drug Facts

OTC - ACTIVE INGREDIENT

Sodium Fluoride 0.044% w/w (0.02% w/v fluoride ion)

OTC - PURPOSE

Anticavity

Approved Uses

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

Warnings

- Please keep out of reach of children.
- If more than used for rinsing is accidentally swallowed get medical help or contact a Poison Control Center right away. Use only under guidance or supervision of a dentist or doctor.

Directions: This is a fluoride treatment rinse, not a mouthwash. Read directions carefully before using.

Adults and Children 6 yrs and older	Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 ml of rinse between your teeth for one minute, then spit out. **Do not swallow the rinse.** Do not eat or drink for 30 minutes after rinsing.
Children 6 to 12	Instruct and supervise in good rinsing (to minimize swallowing).
Children Under 6	Consult a dentist or doctor.

Inactive Ingredients:

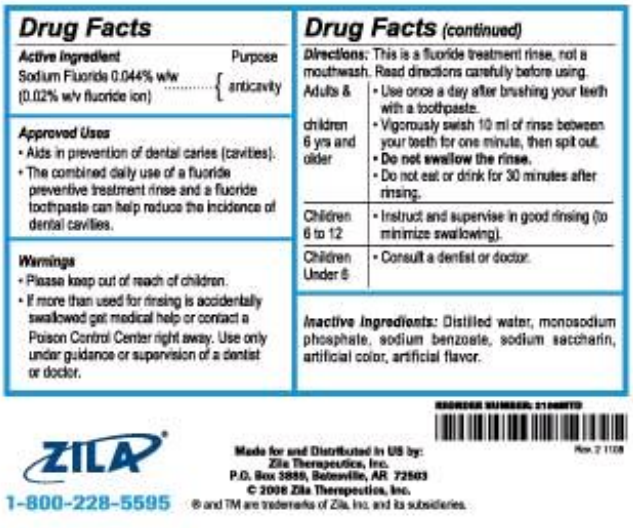
Distilled water, monosodium phosphate, sodium benzoate, sodium saccharin, artificial color, artificial flavor.

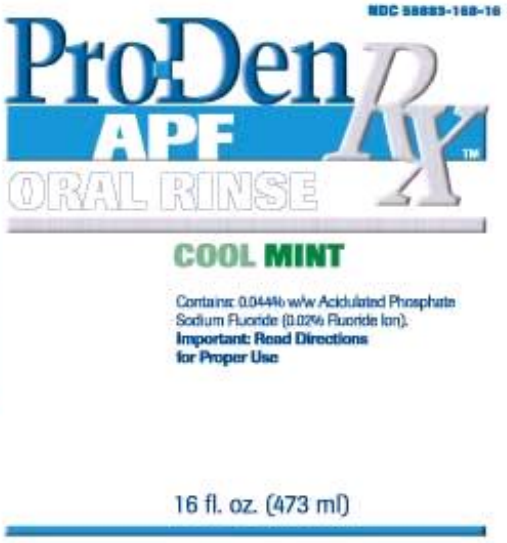
Made for and Distributed in US by:
Zila Therapeutics, Inc.,

P.O. Box 3889, Batesville, AR 72503

1-800-228-5595

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





PRO-DEN RX

sodium fluoride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59883-168
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.044 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC ANHYDROUS (UNII: KH7I04HPUU)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59883-168-16	473 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/21/2008	

Labeler - Zila Therapeutics, Inc. (883514127)

Establishment

Name	Address	ID/FEI	Business Operations
Zila Therapeutics, Inc.		883514127	MANUFACTURE

Revised: 8/2010 Zila Therapeutics, Inc.