

**DENTALCLEAN REGENERATOR SENSITIVE DENTAL GEL WITH FLOURIDE-  
sodium fluoride 0.24% paste, dentifrice  
Rabbit Indústria e Comércio de Produtos de Higiene Pessoal Ltda**

-----  
**Dentalclean Regenerator Sensitive Dental Gel with Flouride**

Sodium fluoride 0.24%

Anticavity

**Use**aids in the prevention of dental cavities

**WARNINGS:** If more than used for brushing is accidentally swallowed, get medical help or contact poison control center right away.

**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.
- Children 2 to 6 years of age: instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children under 6 years as necessary and use a pea-sized amount until your child is capable of using without supervision.
- Children under 2 years of age: do not use unless directed by a dentist or doctor or as directed by a dentist or doctor.

Store in a dry, cool place away from sunlight.

Glycerol, Silium Dioxide, Sorbitol, Water, Sodium Lauryl Sulphate, Aroma, Carmelose Sodium, Phoshoric Acid, Tetrassodium Pyrophosphate, Menthol, Mica, Cetylpyridinium Chloride, Sodium Benzoate, Sucralose

Keep out of reach of children under 6 years of age

YELLOW  
LACE  
GLUE



YELLOW  
LACE  
GLUE

YELLOW  
LACE  
GLUE



YELLOW  
LACE  
GLUE

YELLOW  
LACE  
GLUE



YELLOW  
LACE  
GLUE

YELLOW  
LACE  
GLUE



YELLOW  
LACE  
GLUE

**Drug Facts**

**Active Ingredients** Purpose  
Sodium Fluoride 0.243% Anticavity  
(0.11% w/v fluoride ion)

**Uses** • Use in the prevention of dental caries.

**Warnings**  
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.

**Drug facts (continued)**

**Directions**  
• Adults and children of 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least before a day, or as directed by a dentist or doctor.  
• Children of 2 to 6 years of age: brush teeth under 6 years of age in local brushing and flossing inside the individual's mouth. Supervise children under 6 years of age or necessary and use a pea-sized amount until your child is capable of using without supervision.  
• Children under 2 years of age: do not use unless directed by a dentist or doctor.

**Drug facts (continued)**

**Other Information**  
Store in a dry cool place away from sunlight.

**Sensitive Ingredients**  
Glycerol, Ethyl Alcohol, Saccharin, Methyl Salicylate, Sodium Lauryl Sulfate, Aspartame, Carboxymethyl Cellulose, Polyethylene Glycol, Tetrasodium Pyrophosphate, Sorbitol, Maltol, Maltolol, Cellulose Graft Copolymer, Sodium Bicarbonate, Saccharin.

DENTALCLEN, LLC  
11224 2nd Street  
Miami, FL 33131 USA  
www.dentalclem.com  
CUSTOMER SERVICE  
1-800-234-2322  
©2014 DentalClen, LLC  
DENTALCLEN IS A TRADEMARK OF DENTALCLEN, LLC



7 698185 414131



# DENTALCLEAN REGENERATOR SENSITIVE DENTAL GEL WITH FLUORIDE

sodium fluoride 0.24% paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84035-002
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.4 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>CETYLPIRIDINIUM CHLORIDE ANHYDROUS</b> (UNII: 6BR7T22E2S)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>GLYCEROL FORMAL</b> (UNII: 3L7GR2604E)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>MICA</b> (UNII: V8A1AW0880)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84035-002-03	1 in 1 CARTON	06/01/2024	
1		104 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 Drug	M021	06/01/2024	

**Labeler** - Rabbit Indústria e Comércio de Produtos de Higiene Pessoal Ltda (901719567)

### Establishment

Name	Address	ID/FEI	Business Operations
Rabbit Indústria e Comércio de Produtos de Higiene Pessoal Ltda		901719567	manufacture(84035-002)

Revised: 5/2024

Rabbit Indústria e Comércio de Produtos de Higiene Pessoal Ltda