

**SOOM MOUTHWASH- sodium fluoride, allantoin liquid  
TECOZYME 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.*

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Sodium Fluoride, allantoin

- Help teeth whitening and reduce of bad breath
- Aids in the prevention of gingivitis, periodontitis

Keep out of reach of children

Adults and children 6 years of age and older

- Vigorously swish 11 mL between teeth twice a day for 30 seconds then spit out.
- Do not swallow
- Children under 6 years of age: do not use

Do not use in Children under 6 years of age

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

Water, Erythritol, Xylitol, Sodium Benzoate, Glycerin, Propylene Glycol, PEG-40 Hydrogenated Caster Oil, L-Menthol, Zinc Gluconate, Sodium Citrate, Fragrance

For dental use only

**Product name: Soom Mouthwash**

Volume: 11 ml \*20



**Drug Facts**

**Active Ingredients**

	<i>Purpose</i>
Sodium Fluoride 0.02 % -----	Anticavity
Allantoin 0.051% -----	Skin Protectant

**Uses**

- Help teeth whitening and reduce of bad breath
- Aids in the prevention of gingivitis, periodontitis

**Warning**

**Do not use in Children** under 6 years of age  
 If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Adults and children 6 years of age and older**
- Vigorously swish 11 mL between teeth twice a day for 30 seconds then spit out.
  - Do not swallow
  - Children under 6 years of age: do not use

**Other Information**

- Read the directions and warnings before use
- Store at room temperature
- This rinse is not intended to replace brushing or flossing

**Inactive Ingredients**

Water, Erythritol, Xylitol, Sodium Benzoate, Glycerin, Propylene Glycol, PEG-40 Hydrogenated Caster Oil, L-Menthol, Zinc Gluconate, Sodium Citrate, Fragrance

**[DISTRIBUTED BY]**



101, Daehak-ro, Jongno-gu, Seoul, Republic of Korea

**SOOM MOUTHWASH**

sodium fluoride, allantoin liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79717-0001
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79717-0001-1	11 mL in 1 POUCH; Type 0: Not a Combination Product	07/24/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/24/2020	

**Labeler** - TECOZYME INC (694613703)**Registrant** - TECOZYME INC (694613703)**Establishment**

Name	Address	ID/FEI	Business Operations
TECOZYME INC		694613703	manufacture(79717-0001)

Revised: 7/2020

TECOZYME INC