

**TheraBreath Healthy Smile Oral Rinse- sodium fluoride rinse**  
**Dr. Harold Katz, LLC**

*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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**TheraBreath Healthy Smile Oral Rinse**

**Active Ingredient**

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

**Purpose**

Anticavity

**Uses**

Aids in the prevention of dental cavities

**Warnings**

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

**Warnings**

**Directions**

Adults and Children 6 years of age and older:

- Use once a day after brushing your teeth with a toothpaste.
- Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out.
- Do not swallow the rinse.
- Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: consult a dentist or doctor.

**Other Information**

Do not use if safety seal is broken or missing.

## Inactive Ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Citric Acid, Sodium Hydroxide, Sodium Chlorite, Menthol, Citrus Lemon Peel Oil, Mentha Piperita Oil, Sodium Benzoate, Sucralose, Xylitol, Sodium Bicarbonate.

## TheraBreath Healthy Smile Oral Rinse



## Healthy Smile Travel Size



Healthy Smile Travel Pouch 0.25 oz



# THERABREATH HEALTHY SMILE ORAL RINSE

sodium fluoride rinse

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72551-246
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.0005 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>LEMON OIL</b> (UNII: I9GRO824LL)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3Z D4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>PEG-40 CASTOR OIL</b> (UNII: 4ERD2076EF)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SODIUM CHLORITE</b> (UNII: G538EBV4VF)	
<b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Product Characteristics

<b>Color</b>	white (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Clean Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-246-01	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
2	NDC:72551-246-02	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
3	NDC:72551-246-03	7 g in 1 POUCH; Type 0: Not a Combination Product	03/19/2019	
4	NDC:72551-246-04	958.21 g in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/02/2018	

**Labeler** - Dr. Harold Katz, LLC (965507767)

Revised: 2/2022

Dr. Harold Katz, LLC