

THERABREATH AM-PM TWIN PACK- sodium fluoride
Church & Dwight Co., Inc.

Drug Facts

Overnight Oral Rinse

Active ingredient

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

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warning

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get help or contact a Poison Control Center right away.

Directions

Adults 18 years of age or 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 30 minutes after rinsing

Inactive ingredients

water, glycerin, PEG-40 hydrogenated castor oil, citric acid, menthol, sodium benzoate, sodium bicarbonate, sodium chlorite, sodium hydroxide, sucralose, flavor

Principal Display Panel

TheraBreath AM + PM TWIN PACK

AM

POWERED BY OXYGEN TM

INVIGORATING ICY MINT

1	NDC:10237-268-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	02/03/2025	
---	------------------	--	------------	--

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	473 mL
Part 2	1 BOTTLE, PLASTIC	473 mL

Part 1 of 2

THERABREATH OVERNIGHT CHAMOMILE MINT

sodium fluoride rinse

Product Information

Item Code (Source)	NDC:10237-262
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORITE (UNII: G538EBV4VF)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT, MENTHOL	Imprint Code	
Contains			

Packaging

#	Item	Package Description	Marketing Start	Marketing End
---	------	---------------------	-----------------	---------------

#	Code	Package Description	Date	Date
1		473 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/22/2024	

Part 2 of 2	
THERABREATH FRESH BREATH ORAL RINSE INVIGORATING ICY MINT mouthwashes and breath fresheners (liquids and sprays) [oral products] liquid	

Product Information	
Route of Administration	ORAL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		473 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		06/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	02/03/2025	

Labeler - Church & Dwight Co., Inc. (001211952)