

SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR CLEAN MINT- sodium fluoride liquid

SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR EXTRA FRESH- sodium fluoride liquid

Haleon US Holdings LLC

Drug Facts

Active ingredient

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

Purpose

Anticavity

Uses

- aids in the prevention of dental cavities.
- the combined daily use of a fluoride preventive treatment rinse and a fluoride toothpaste can help reduce the incidence of dental cavities.

Warning

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.

Directions

- **adults and children 6 years of age and older:**
 - use once a day after brushing your teeth with a toothpaste.
 - pour 10 milliliters into cap (10 mL mark on inside of cap); do not fill above the 10 mL mark.
 - vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out.
 - do not swallow the rinse.
 - do not drink from the bottle.
 - do not rinse mouth with water.
 - 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 store above 25°C (77°F)

Inactive ingredients (Clean Mint)

water, sorbitol, sodium benzoate, poloxamer 407, benzyl alcohol, polysorbate 20, flavor, propylene glycol, sodium saccharin, disodium EDTA, disodium phosphate, monosodium phosphate, calcium disodium EDTA, cetylpyridinium chloride, potassium sorbate

Inactive ingredients (Extra Fresh)

water, sorbitol, sodium benzoate, poloxamer 407, benzyl alcohol, polysorbate 20, flavor, propylene glycol, sodium saccharin, disodium EDTA, disodium phosphate, monosodium phosphate, calcium disodium EDTA, cetylpyridinium chloride, potassium sorbate, FD&C blue no. 1

Questions or comments?

1-866-844-2797

Other Information

Re-mineralizing action for strong and protected teeth*

- ✓ Alcohol Free**
- ✓ SLS Free
- ✓ Paraben Free
- ✓ Dye Free

ALWAYS FOLLOW THE LABEL

Do not use if printed safety seal around cap is broken or missing.

*when used as directed with a fluoride toothpaste

**contains no ethanol

Distributed by: Haleon, Warren, NJ 07059

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Made in Taiwan

Principal Display Panel (Clean Mint)

New

SENSODYNE

PRONAMEL

ANTICAVITY FLUORIDE MOUTHWASH

INTENSIVE ENAMEL

REPAIR

CLEAN MINT

Cavity
Protection

Alcohol
Free**

Helps actively repair weakened enamel*

IMPORTANT: Read directions for proper use

16.9 FL OZ (500 mL)

Front: 204828

Back: 204832



Principal Display Panel (Extra Fresh)

New

SENSODYNE

PRONAMEL

ANTICAVITY FLUORIDE MOUTHWASH

INTENSIVE ENAMEL

REPAIR

EXTRA FRESH

Cavity

Protection

Alcohol
Free**

Helps actively repair weakened enamel*

IMPORTANT: Read directions for proper use

16.9 FL OZ (500 mL)

Front: 204830

Back: 204831



SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR CLEAN MINT

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0449
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0449-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2024	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M022	01/02/2024	

SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR EXTRA FRESH

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0451
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0451-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/02/2024	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 10/2024

Haleon US Holdings LLC