PROPOLIMIX- sodium fluoride, allantoin liquid
Pharmacal-International. Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredients **Purpose**

SODIUM FLUORIDE 0.02% .....Anticavity
Allantoin 0.2% ..... Antigingivitis

Purpose

Anticavity, Antigingivitis, Clean mouth

Use

- Aids in prevention of dental cavities.
- Helps prevent and reduce plague (antiplague).
- Helps to remove bad breath.

Warnings

- Be careful not to swallow and rinse your mouth thoroughly after use.
- Stop use and ask a dentist if oral irritation or tooth sensitivity occurs
- Keep out of reach of children under the age of six, and if children under the age of six swallow large amounts, contact your doctor or dentist immediately.

Directions

Rinse mouth with this about 10~15ml for 30 seconds then expel

Average daily dose
Use twice a day after brushing, meals, and before social occasions.

Inactive Ingredients

Glycerin, Xylitol, Sodium saccharin, Chitosan, Sodium benzoate, Citric acid, Sodium citrate, DL-malic acid, Acetic acid, Greentea extract, Turmeric extract, Ginger tincture, Propolis extract, Flavoring, Peppermint oil, L-menthol, Caramel coloring, Purified water

Storage method

storage at room temperature (1~30℃)

Expiration date

Separately marked

Product label

Drug Facts

Active Ingredients	Purpose
SODIUM FLUORIDE 0.02%	Anticavity
Allantoin 0.2%	Antigingivitis

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PROPOLIMIX

sodium fluoride, allantoin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24765-002
Route of Administration	ORAL		

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
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLIGLUSAM (UNII: 82LKS4QV2Y)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALIC ACID (UNII: 817L1N4CKP)	
ACETIC ACID (UNII: Q40Q9N063P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TURMERIC (UNII: 856YO1Z64F)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
2-(L-MENTHOXY)ETHANOL (UNII: 5ZWW23169H)	
CARAMEL (UNII: T9D99G2B1R)	
WATER (UNII: 059QF0KO0R)	
GINGER (UNII: C5529G5JPQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24765-002-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2024	

Labeler - Pharmacal-International. Co., Ltd. (557805060)

Revised: 10/2024 Pharmacal-International. Co., Ltd.