KILLFIRE MOUTHWASH- sodium fluoride rinse
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 ingredient

Sodium Fluoride (0.02%)

Purpose

- Anticavity mouthwash

Use

- Aids in prevention of dental cavities

Directions

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

Average daily dose

- Use twice a day after brushing, meals, and before social occasions.

Warnings

- **Keep out of reach of children.**
- Children under 7 years or younger must have parent supervision.
- Do not swallow. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Inactive Ingredients

Sodium Fluoride, Allantoin, Glycerin, Xylitol, Acetic acid, Sodium acetate, Malic acid, Sodium Benzoate, GreenTea Extract, Sodium Saccharin, flavoring, Polyoxyethylenehardened castor oil, L-Menthol, Cacao Color, Purified water

Product label

Drug Facts

Active Ingredients	**Purpose**
SODIUM FLUORIDE 0.02%	Anticavity mouthwash

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Expiration date

- Separately marked

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KILLFIRE MOUTHWASH

sodium fluoride rinse

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24765-132
Route of Administration	ORAL		

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

UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
ACETIC ACID (UNII: Q40Q9N063P)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
MALIC ACID (UNII: 817L1N4CKP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
RACEMENTHOL (UNII: YS08XHA860)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24765-132-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/25/2021	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Ecoworld Co .,ltd		688735061	manufacture(24765-132)

Revised: 8/2023 Pharmacal-International. Co., Ltd.