OPRECARE 21- sodium monofluorophosphate gel
O'PRECARE

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.

O'PRECARE 21

Active ingredient

Sodium Monofluorophosphate (0.6%)

Purpose

Anticavity

Warnings

When using this product, if irritation occurs stop use and ask a dentist. Do not swallow, and rinse enough after use. Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center right away.

Uses

Helps protect against cavities, plaque, gingivitis

Directions

Directions	
Adults and children 2 years of age and older	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
Children 2 to 6 years	Use only a pea sized amount and supervise childs brushing and rinsing (to minimize swallowing)
Children under 2 years	Ask a dentist or physician

Keep out of reach of children

Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center right away.

Inactive ingredients

Silica, Tocopheryl Acetate, Piridokssin Hydrochloride, Sodium Pyrophosphate, Sorbitol, PEG-32, Hydrated Silica, Cellulose Gum, Titanium Oxide, Xylitol, Stevioside, Camellia Sinensis Leaf Extract, Sodium Methyl Cocoyl Taurate, Ubidecarenone, Cnidium Extract, Menthol, Mint Flavor (Fragrance), Chamomilla Recutita (Matricaria) Flower Extract, Peppermint Flavor (fragrance), D.I-WATER

O'PRECARE 21

OPRECARE 21

sodium monofluorophosphate gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71764-102
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.36 g in 60 g

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Sorbitol (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
Xylitol (UNII: VCQ006KQ1E)	
Stevioside (UNII: 0YON5MXJ9P)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
Menthol (UNII: L7T10EIP3A)	
LICORICE (UNII: 61ZBX54883)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
Allantoin (UNII: 344S277G0Z)	
PIRIDOCAINE HYDROCHLORIDE (UNII: VG6P406YHV)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
Lemon Oil (UNII: I9GRO824LL)	
Orange Oil (UNII: AKN3KSD11B)	
Eucalyptus Oil (UNII: 2R04ONI662)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71764-102-02	1 in 1 PACKAGE	10/12/2017	
1	NDC:71764-102-01	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/12/2017	

Labeler - O'PRECARE (694604592)

Registrant - O'PRECARE (694604592)

Establishment

Name	Address	ID/FEI	Business Operations
O'PRECARE		694604592	relabel(71764-102)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(71764-102)

Revised: 10/2017 O'PRECARE