OPRECARE 3SET (07,12,21)- sodium monofluorophosphate, silicon dioxide
O'PRECARE

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.

O'PRECARE TOOTHPASTE 3SET (07,12,21)

Active ingredient

Active ingredients	
O'PRECARE 07	Sodium Monofluorophosphate (0.6%)
O'PRECARE 12	Silica (Silicon dioxide) (2.85%)
O'PRECARE 21	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

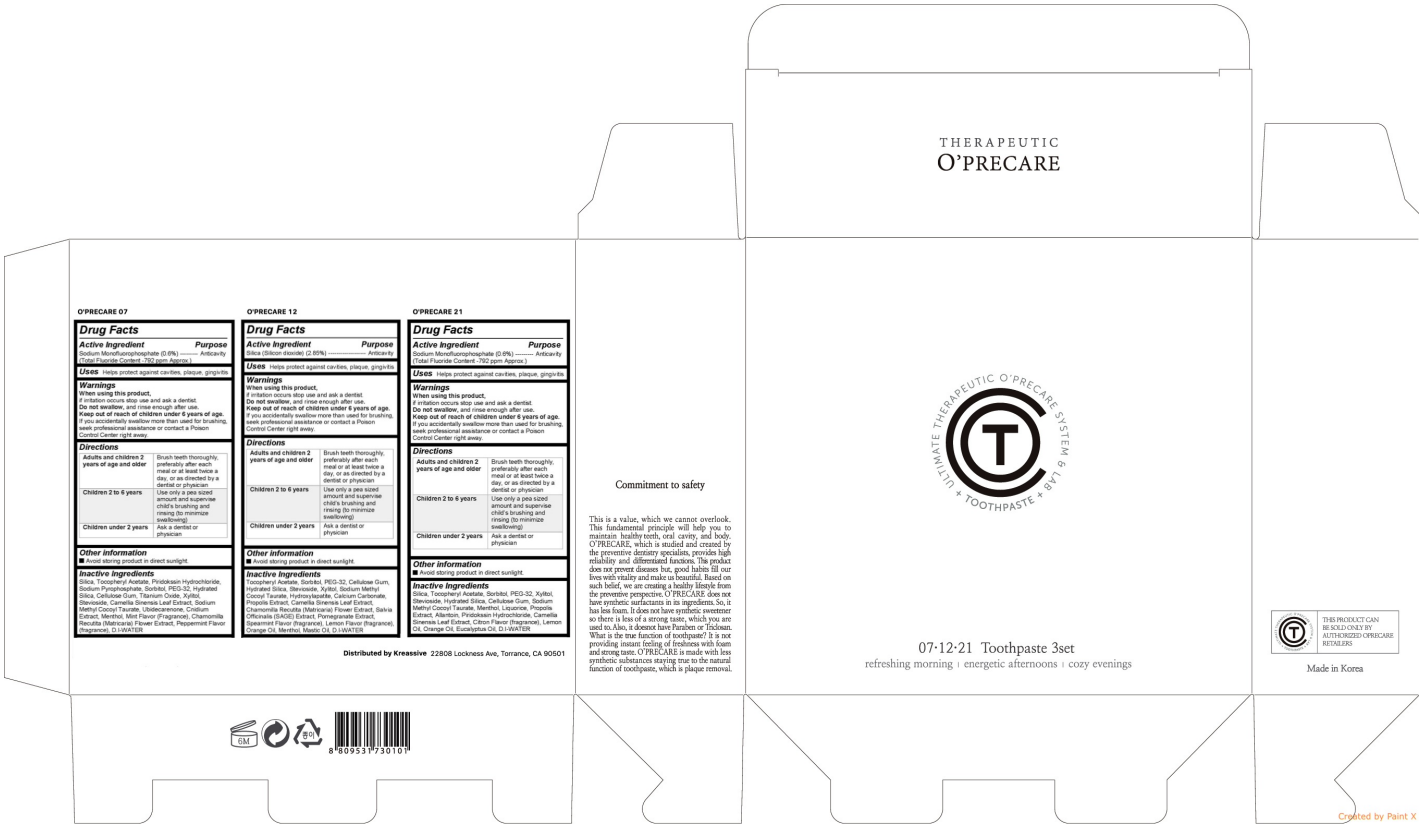
Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center right away.

Inactive ingredients

Inactive ingredients
Silica, Tocopheryl Acetate, Piridokssin Hydrochloride,

O'PRECARE 07	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 12	Tocopheryl Acetate, Sorbitol, PEG-32, Cellulose Gum, Hydrated Silica, Stevioside, Xylitol, Sodium Methyl Cocoyl Taurate, Hydroxylapatite, Calcium Carbonate, Propolis Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Officinalis (SAGE) Extract, Pomegranate Extract, Spearmint Flavor (fragrance), Lemon Flavor (fragrance), Orange Oil, Menthol, Mastic Oil, D.I-WATER
O'PRECARE 21	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 TOOTHPASTE 3SET (07,12,21)



OPRECARE 3SET (07,12,21)

sodium monofluorophosphate, silicon dioxide kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71764-104

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71764-104-01	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	10/12/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PUMP	60 g
Part 2	1 BOTTLE, PUMP	60 g
Part 3	1 BOTTLE, PUMP	60 g

Part 1 of 3

OPRECARE 07

sodium monofluorophosphate paste

Product Information	
Item Code (Source)	NDC:71764-100
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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XYLITOL (UNII: VCQ006KQ1E)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
UBIDECARENONE (UNII: EJ27X76M46)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

STEVIOSIDE (UNII: 0YON5MXJ9P)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHAMOMILE (UNII: FGL3685T2X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71764-100-02	1 in 1 PACKAGE		
1	NDC:71764-100-01	60 g in 1 BOTTLE, PUMP; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Part 2 of 3

OPRECARE 12

silicon dioxide gel

Product Information

Item Code (Source)	NDC:71764-101
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	1.71 g in 60 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
STEVIOSIDE (UNII: 0YON5MXJ9P)	
Xylitol (UNII: VCQ006KQ1E)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
Calcium Carbonate (UNII: H0G9379FGK)	

PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
SALVIA OFFICINALIS ROOT (UNII: 236QY0A1BL)	
POMEGRANATE (UNII: 56687D1Z4D)	
ORANGE OIL (UNII: AKN3KSD11B)	
Menthol (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71764-101-02	1 in 1 PACKAGE		
1	NDC:71764-101-01	60 g in 1 BOTTLE, PUMP; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/12/2017	

Part 3 of 3

OPRECARE 21

sodium monofluorophosphate gel

Product Information

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		
1	NDC:71764-102-01	60 g in 1 BOTTLE, PUMP; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/12/2017	

Labeler - O'PRECARE (694604592)

Registrant - O'PRECARE (694604592)

Establishment

Name	Address	ID/FEI	Business Operations
O'PRECARE		694604592	relabel(71764-104)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(71764-104)