

OPREKARE 21- sodium monofluorophosphate gel

O'PREKARE

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'PREKARE 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 child's 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, Piridoksin 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'PREKARE 21

THERAPEUTIC
O'PRECARE

21



Commitment to safety

This is a value, which we cannot overlook. This fundamental principle will help you to maintain healthy teeth, oral cavity, and body. O'PRECARE, which is studied and created by the preventive dentistry specialists, provides high reliability and differentiated functions. This product does not prevent diseases but, good habits fill our lives with vitality and make us beautiful. Based on such belief, we are creating a healthy lifestyle from the preventive perspective. O'PRECARE does not have synthetic surfactants in its ingredients. So, it has less foam. It does not have synthetic sweetener so there is less of a strong taste, which you are used to. Also, it does not have Paraben or Triclosan. What is the true function of toothpaste? It is not providing instant feeling of freshness with foam and strong taste. O'PRECARE is made with less synthetic substances staying true to the natural function of toothpaste, which is plaque removal.

Drug Facts

Active Ingredient **Purpose**
Sodium Monofluorophosphate (0.6%) ----- Anticavity
(Total Fluoride Content - 792 ppm Approx.)

Uses Helps protect against cavities, plaque, gingivitis

Warnings

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if irritation occurs stop use and ask a dentist.
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If you accidentally swallow more than used for brushing,
seek professional assistance or contact a Poison
Control Center right away.

Directions

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Children under 2 years	Ask a dentist or physician

Other information

■ Avoid storing product in direct sunlight.

Inactive Ingredients

Silica, Tocopheryl Acetate, Sorbitol, PEG-32, Xylitol, Stevioside, Hydrated Silica, Cellulose Gum, Sodium Methyl Cocoyl Taurate, Menthol, Liquorice, Propolis Extract, Allantoin, Pridoksin Hydrochloride, Camellia Sinesis Leaf Extract, Citron Flavor (fragrance), Lemon Oil, Orange Oil, Eucalyptus Oil, DI-WATER

Distributed by Kreassive

22808 Lockness Ave, Torrance, CA 90501

Essence toothpaste
for cozy evenings
Pasta dental Essence para
una noche tranquila
dentifrice du sérum pour
le soir agréable

溫馨傍晚必備精華牙膏
溫馨傍晚必備精華牙膏

心地よい夜のための
エッセンス歯みがき粉

아늑한 저녁을 위한 에센스 치약

60g e (2.0 oz.)

Made in Korea
www.oprecare.com

THIS PRODUCT CAN
BE SOLD ONLY BY
AUTHORIZED O'PRECARE
RETAILERS



PZN - 156874615



Created by Paint X

OPREKARE 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