

## **OPREKARE 12- silicon dioxide gel**

### **O'PREKARE**

*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'PREKARE 12**

#### **Active ingredient**

Silica (Silicon dioxide) (2.85%)

#### **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**

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'PREKARE 12**

THERAPEUTIC  
O'PRECARE

# 12



### 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.

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Silica (Silicon dioxide) (2.85%)	Anticavity
<b>Uses</b> Helps protect against cavities, plaque, gingivitis	
<b>Warnings</b>	
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.	
<b>Directions</b>	
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
<b>Other information</b>	
Avoid storing product in direct sunlight	
<b>Inactive Ingredients</b>	
Tocopheryl Acetate, Sorbitol, PEG-32, Cellulose Gum, Hydrated Silica, Stevioside, Xylitol, Sodium Methyl Cocoyl Taurate, Hydroxyapatite, 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	
<b>Distributed by Kreassive</b>	
22808 Lockness Ave, Torrance, CA 90501	

Essence toothpaste  
for energetic afternoons

Pasta dental Essence para  
un almuerzo energético

dentifrice du sérum pour  
le déjeuner dynamique

活力午後必備精華牙膏  
活力午後必備精華牙膏

活発な昼のための  
エッセンス歯みがき粉

활기찬 점심을 위한 에센스 치약

Made in Korea  
www.oprecare.com

60g e (2.0 oz.)

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



PZN - 156874615



Created by Paint X

## OPREKARE 12

silicon dioxide gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71764-101
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
STEVIO SIDE (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	10/12/2017	
1	NDC:71764-101-01	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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(71764-10 1)

## Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(71764-10 1)

Revised: 10/2017

O'PRECARE