

OPREKARE 24- 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 24

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

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

O'PREKARE 24

THERAPEUTIC
O'PRECARE

24

THERAPEUTIC
O'PRECARE



Commitment to safety

This is a value, which we cannot overlook. This fundamental principle will help you to maintain healthyteeth, 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 doesnot 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.

Made in Korea
www.oprecare.com

50g e (1.7 oz.)

Drug Facts

Active Ingredient	Purpose
Silica (Silicon dioxide) (2.85%) ----	Anticavity

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Children under 2 years	Ask a dentist or physician.

Other information
■ Avoid storing product in direct sunlight.

Inactive Ingredients
Tocopheryl Acetate, Sorbitol, PEG-32, Cellulose Gum, Hydrated Silica, Stevioside, Xylitol, Sodium Methyl Cocoyl Taurate, Calcium Carbonate, Propolis Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Officialis (SAGE) Extract, Pomegranate Extract, Ubidecarenone, Hydroxylapatite, Spearmint Flavor (fragrance), Lemon Flavor (fragrance), Orange Oil, Menthol, Mastic Oil, D.I.WATER

Distributed by Kreassive
22808 Lockness Ave, Torrance, CA 90501

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



PZN - 156874615

OPREKARE 24

silicon dioxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71764-103
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	1.425 g in 50 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)	
Calcium Carbonate (UNII: H0G9379FGK)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
SALVIA OFFICINALIS ROOT (UNII: 236QY0A1BL)	
POMEGRANATE (UNII: 56687D1Z4D)	
Ubidecarenone (UNII: EJ27X76M46)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
ORANGE OIL (UNII: AKN3KSD11B)	
Menthol (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71764-103-02	1 in 1 PACKAGE	10/12/2017	
1	NDC:71764-103-01	50 g in 1 TUBE; Type 0: Not a Combination Product		

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(71764-103)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(71764-103)

Revised: 10/2017

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