

DIO ENAMEL COATING PEN PRO TOOTH- tricalcium phosphate, dental type silica, tocopheryl acetate paste, dentifrice
Dio Corporation

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](#).

Tricalcium Phosphate, Dental Type Silica (Silicon Dioxide), Tocopheryl Acetate (.ALPHA.-TOCOPHEROL ACETATE)

For dental care

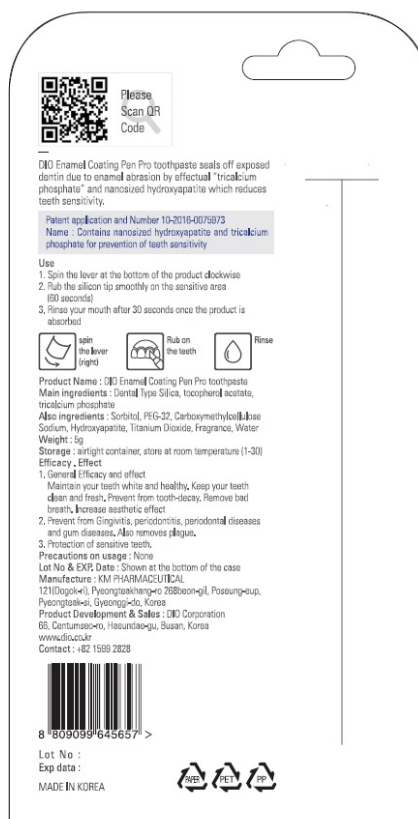
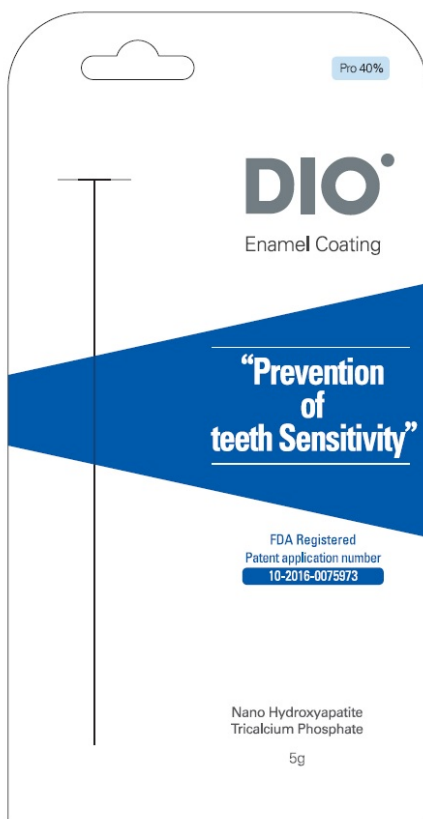
Keep out of reach of children

1. Spin the lever at the bottom of the product clockwise
2. Rub the silicon tip smoothly on the sensitive area (60 seconds)
3. Rinse your mouth after 30 seconds once the product is absorbed)

Alright container, store at room temperature (1-30)

Sorbitol, water, etc.

For dental use only



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75902-6001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICALCIUM PHOSPHATE (UNII: K4C08XP666) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	20 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	0.2 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75902-6001-1	5 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2016	

Labeler - Dio Corporation (631085206)**Establishment**

Name	Address	ID/FEI	Business Operations
KMPharmaceutical Co., Ltd.		688679158	manufacture(75902-6001)

Revised: 6/2017

Dio Corporation