

EXODEN SENSITIVE- tricalcium phosphate, silicon dioxide paste LIFEON Corp.

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.

70602-006_ Exoden Sensitive Toothpaste

Tricalcium Phosphate 19%

Silicon dioxide 2.5%

Anti plaque

Aids in cleanness of teeth and protection of gum health

Supervise children as necessary until capable of using without supervision

Adults and children 6 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 a physician

Children under 12 years: Instruct in good brushing and rinsing habits (to minimize swallowing)

Children under 6 years: Do not use unless directed by a dentist or a physician

Ask a dentist before use if you have

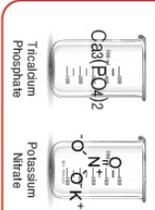
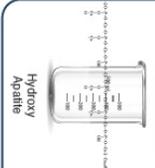
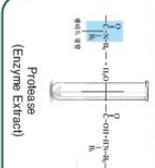
- bleeding or redness lasting more than 2 weeks
- pain, swelling, pus, loose teeth, or more spacing between teeth

These may be signs of periodontitis, a serious form of gum disease

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Glycerin, D-Sorbitol Solution, Carboxymethylcellulose Sodium, Hydroxyapatite, Xylitol, Stevioside, Glycyrrhiza Extract, Protease, Sodium Chloride, Camomille Extract(1), Scutellaria Root Extract, Sage Extract, Gentiana Extract, Fennel Extract , Sodium Cocoyl Glutamate, Tocopheryl Acetate, Mastic Oil, Eucalyptus Globulus Leaf Oil, L-Menthol, Peppermint Oil, Anethole, Carvone, Chamaecyparis Obtusa Oil, Potassium nitrate, Purified Water



TOOTH PASTE	Quasi-drug	TOOTH PASTE	TOOTH PASTE												
<p>Sensitive Tooth Multiple care ingredients</p>  <p>Sensitive Tooth Relaxing ingredients</p>  <p>Sensitive Tooth Strengthening enzyme ingredients</p>  <p>Sensitive teeth to protect Natural ingredients</p> 	<p>EXODEN Sensitive TOOTH PASTE</p> <p>Multiple care ingredients for tooth sensitivity</p> <p>Enhanced care for tooth sensitivity with patented nature-derived ingredients</p>  <p>Tricalcium phosphate Potassium nitrate Hydroxy Apatite Protease</p>  <p>Contains certified plant ingredients.</p> <p>Sensitive Toothpaste</p> <p>120g / 4.23fl.oz. Made in Korea</p>	<p>ISO 국제심사협회 Grand Prize for Quality Satisfaction from ISO International Auditor Association</p> <p>서울의료봉사재단 MOU with Seoul Medical Service Foundation</p> <p>대한예방치과의학회 MOU with Korean Academy of Preventive Dentistry</p> <p>대한치과의사협회 MOU with The Korean Academy of Oral and Maxillofacial Implantology</p> <p>국회 보건복지위원회 National Assembly Health and Welfare Committee Chairman Award</p>	<p>Tooth sensitivity management with multiple care ingredients Contain herbs/mint, good for removing bad breath and cleansing mouth</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purposes</th> </tr> </thead> <tbody> <tr> <td>TRICALCIUM PHOSPHATE 1.9%</td> <td>Anti plaque</td> </tr> <tr> <td>SILICON DIOXIDE 2.50%</td> <td>Anti plaque</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> Aids in the cleanness of teeth and protection of gum health <p>Directions Supervise children as necessary until capable of using without supervision</p> <table border="1"> <thead> <tr> <th>Adults and children 6 years of age and older</th> <th>Children under 12 years</th> <th>Children under 6 years</th> </tr> </thead> <tbody> <tr> <td>Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician</td> <td>Instruct in good brushing and rinsing habits (to minimize swallowing)</td> <td>Do not use unless directed by a dentist or a physician</td> </tr> </tbody> </table> <p>Warnings</p> <ul style="list-style-type: none"> Ask a dentist before use if you have <ul style="list-style-type: none"> bleeding or redness lasting more than 2 weeks pain, swelling, pus, loose teeth, or more spacing between teeth <p>These may be signs of periodontitis, a serious form of gum disease</p> <ul style="list-style-type: none"> Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away <p>Inactive ingredients</p> <p>Glycerin, D-Sorbitol Solution, Carboxymethylcellulose Sodium, Hydroxyapatite, Xylitol, Stevioside, Glycyrrhiza Extract, Protease, Sodium Chloride, Camomille Extract(1), Scutellaria Root Extract, Sage Extract, Gentiana Extract, Fennel Extract, Sodium Cocoyl Glutamate, Tocopheryl Acetate, Mastic Oil, Eucalyptus Globulus Leaf Oil, L-Menthol, Peppermint Oil, Anethole, Carvone, Chamaecyparis Obtusa Oil, Potassium nitrate, Purified Water</p> <p>Other Information</p> <ul style="list-style-type: none"> Store at room temperature <p>● Seller : Lifeon Co., Ltd. #303, 3F, Sejeong IT Building, 10, Toegy-e-ro 36ga-gil, Jung-gu, Seoul</p> <p>● Manufacturer : Korea Life Science Co., Ltd. 683, Cheondeoksan-ro, Wongok-myeon, Anseong-si, Gyeonggi-do, Rep. of Korea</p> 	Active Ingredients	Purposes	TRICALCIUM PHOSPHATE 1.9%	Anti plaque	SILICON DIOXIDE 2.50%	Anti plaque	Adults and children 6 years of age and older	Children under 12 years	Children under 6 years	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or a physician	Instruct in good brushing and rinsing habits (to minimize swallowing)	Do not use unless directed by a dentist or a physician
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<p>Containing nature-derived ingredients</p> <p>EXODEN Sensitive Toothpaste</p> <p>Chamomile extract (USDA) Gentiana extract (USDA) Sage extract (ECOCERT) Protease(enzyme extract), Xylitol, Licorice extract, Bamboo salt(sodium chloride) Gold extract, Fennel extract Eucalyptus oil, Cypress oil</p>	<p>EXODEN</p> <p>+ Household Oral Clinic</p>	<p>Lifeon Co., Ltd. www.lifeon.cc</p> <p>Consumer Service Office 82-2-1577-5907</p> <p>In case of any abnormality, this product is subject to compensation according to the Consumer Dispute Resolution Criteria released by the Fair Trade Commission.</p>	<p>EXODEN</p> <p>+ Household Oral Clinic</p>												
<p>EXODEN Sensitive TOOTH PASTE</p>															

EXODEN SENSITIVE

tricalcium phosphate, silicon dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70602-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICALCIUM PHOSPHATE (UNII: K4C08XP666) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	19 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
XYLITOL (UNII: VCQ006KQ1E)	
GLUCOSYL STEVIOL (UNII: TKD5UC898Q)	
LICORICE (UNII: 61ZBX54883)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CHAMOMILE (UNII: FGL3685T2X)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
CLARY SAGE (UNII: U3HSK5JC0Q)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ANETHOLE (UNII: Q3JEK5DO4K)	
CARVONE, (+/-)- (UNII: 75GK9XIA8I)	
CHAMAECYPARIS OBTUSA WOOD OIL (UNII: P2OMP71Y62)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70602-006-02	1 in 1 CARTON	03/11/2021	
1	NDC:70602-006-01	120 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		03/11/2021	

Labeler - LIFEON Corp. (688528872)

Registrant - LIFEON Corp. (688528872)

Establishment

Name	Address	ID/FEI	Business Operations
Korea Life Science Co.,Ltd		694914835	manufacture(70602-006)

Revised: 3/2021

LIFEON Corp.