

**IODENT SENSITIVE- potassium nitrate,sodium fluoride paste
Zhaoqing Longda Biotechnology Co., Ltd.**

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.

72129 002 Potassium Nitrate Sodium Fluoride

Active Ingredient

Potassium Nitrate 5%

Sodium Fluoride . 0.15%

Purpose

Antihypersensitivity

Anticavity

Use

Builds increasing protection against painful sensitivity of the teeth due to cold , heat , acids, sweets or contact.

Aids in the prevention of dental cavities

Warning

Stop use and ask a dentist if

The problem persists or worsens. Sensitive teeth may indicate a serious problem that may prompt care by a dentist

Pain/sensitivity still persists after 4 weeks of use

Directions

Adults and children 12 years of age and older

Apply at least at 1-inch strip of product onto a soft bristle toothbrush

Brush teeth thoroughly for at least 1 minute twice a day(morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing , Spit out after brushing.

Children under 12 years of age:consult a dentist or doctor

Inactive Ingredients

calcium carbonate , water, sorbitol , silica, polyethylene glycol 400, sodium laury alcohol, sodium carboxymethyl cellulose, flavor, sodium saccharin, methylparaben, propylparaben , sodium hydroxide

Keep out of reach of children under 6 years of age

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

<table border="1"> <tr> <td> Drug Facts Active ingredients Potassium nitrate 5% Sodium fluoride (0.15% w/v fluoride ion) </td> <td> Purpose Antihypersensitivity Analgesic </td> </tr> <tr> <td> Uses ■ builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact ■ aids in the prevention of dental cavities </td> <td> 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 doctor. ■ Instruct children under 6 years of age in good brushing and rinsing habits to minimize swallowing. ■ Supervise children as necessary until capable of using without supervision. ■ children under 2 years of age: consult a dentist or doctor </td> </tr> <tr> <td> Warnings Stop use and ask a dentist if ■ the problem persists or worsens. Sensitivity teeth may indicate a serious problem that may prompt care by a dentist ■ pain/sensitivity still persists after 4 weeks of use 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 (1-800-222-1222) right away. </td> <td> Other information ■ store at room temperature. ■ lot no. & exp date: see box or see crimp of tube Inactive ingredients sorbitol, water, silica, sodium laury alcohol, polyethylene glycol 300, sodium carboxymethyl cellulose, flavor, PES/PPS 116SE copolymer, titanium dioxide, sodium saccharin, sodium hydroxide, sodium pyrophosphate, acid yellow 23, acid blue 1 Questions or comments? call 1-800-814-8028, Monday-Friday, 9AM-5PM (PST) </td> </tr> </table>	Drug Facts Active ingredients Potassium nitrate 5% Sodium fluoride (0.15% w/v fluoride ion)	Purpose Antihypersensitivity Analgesic	Uses ■ builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact ■ aids in the prevention of dental cavities	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 doctor. ■ Instruct children under 6 years of age in good brushing and rinsing habits to minimize swallowing. ■ Supervise children as necessary until capable of using without supervision. ■ children under 2 years of age: consult a dentist or doctor	Warnings Stop use and ask a dentist if ■ the problem persists or worsens. Sensitivity teeth may indicate a serious problem that may prompt care by a dentist ■ pain/sensitivity still persists after 4 weeks of use 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 (1-800-222-1222) right away.	Other information ■ store at room temperature. ■ lot no. & exp date: see box or see crimp of tube Inactive ingredients sorbitol, water, silica, sodium laury alcohol, polyethylene glycol 300, sodium carboxymethyl cellulose, flavor, PES/PPS 116SE copolymer, titanium dioxide, sodium saccharin, sodium hydroxide, sodium pyrophosphate, acid yellow 23, acid blue 1 Questions or comments? call 1-800-814-8028, Monday-Friday, 9AM-5PM (PST)	LOT:HH003-7 EXP:09/2020
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	Distributed by: United Exchange Corp. 17211 Valley View Ave. Centrose, CA 90705 U.S.A. WWW.UXCORP.COM Toll Free: 1 800 814 8028 Made in China This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare L.P. owner of the registered trademark Sensodyne® Fresh Mint.	Brushing twice a day with Iodent® Sensitive toothpaste with fluoride builds a protective coating against painful sensitivity. ■ Contains potassium nitrate to reduce painful sensitivity ■ Cavity protection formula ■ Freshens breath ■ Helps remove stains and whitens teeth					
		For Sensitive Teeth and Cavity Protection IMPORTANT! Read directions for proper use.					
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IODENT SENSITIVE			
potassium nitrate, sodium fluoride paste			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72129-002
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g
	POTASSIUM NITRATE (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
SODIUM CARBOXYMETHYL .BETA.-GLUCAN (DS 0.65-0.85) (UNII: 2YGO1190AP)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
SORBITOL (UNII: 506T60A25R)	
PEG/PPG-116/66 COPOLYMER (UNII: JPOCK963E0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72129-002-01	24 in 1 BOX	02/02/2018	
1		12 in 1 PACKAGE		
1		113 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
OTC monograph not final	part356	02/02/2018	

Labeler - Zhaoqing Longda Biotechnology Co., Ltd. (546452557)

Establishment

Name	Address	ID/FEI	Business Operations
Zhaoqing Longda Biotechnology Co., Ltd.		546452557	manufacture(72129-002)

Revised: 2/2022

Zhaoqing Longda Biotechnology Co., Ltd.