BOTAO KIDS STRAWBERRY FLAVORED WITH FLUORIDE- botao kids strawberry flavored toothpaste with fluoride paste Peer Pharm 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.

Drug Facts

Active Ingredients

Sodium Fluoride 0.225% (0.122% w/v fluoride ion)

Purpose

Anticavity

Uses

Helps to maintain and protect teeth and gums from the very first tooth

Warnings

Keep out of reach of children under 6 yeras of age.

If more than amount used for brushing is swallowed, get medical help or contact a Poison Control Center right away. Do not use if the seal is broken.

Directions

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 2 to 6 years	Use only a pea sized amount and supervise childs brushing and rinsing to minimize swallowing	
Children under 2 years	Ask a dentist or physician	

Directions

• 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 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

Directions

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Inactive Ingredients

Aqua, Glyceryl Stearate SE, Cetyl Alcohol, Butyrospermum Parkii (Shea) Butter, Ricinus Communis (Castor) Seed Oil, Glycerin, Microcrystalline Cellulose, Caprylhydroxamic Acid, Xanthan Gum, Caprylyl Glycol, Bisabolol, Propanediol, Sodium Phytate, Chamomilla Recutita (Matricaria) Flower Extract, Calendula Officinalis Flower Extract, Aloe Barbadensis Leaf Juice

Questions or comments

Call 951-297-7976 or visit www.botaobaby.com

Product label



Inactive ingredients

Children under 2

Xylitol, Aqua, Glycerin, Silica, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, Citric Acid, Chamomilla Recutita (Matricaria) Flower Extract, Calendula Officinalis Flower Extract, Aloe Barbadensis Leaf Juice, Fragaria Chiloensis (Strawberry) Fruit Extract.

swallowing

Ask a dentist or

Questions or comments

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BOTAO Kids Strawberry Flavored Toothpaste

Anticavity with fluoride

Protects against tooth decay. Helps to maintain and protect teeth and gums.

We at BOTAO have created an ultra delicate formula, that contains Fluoride to protect against tooth decay, and other natural ingredients: Xylitol, Calendula, Chamomile and Aloe Vera to sooth discomfort.

These natural ingredients make BOTAO toothpaste the natural choice in caring for your baby – your way.

- No parabens, no sulfates, no SLS, no artificial flavor, dyes or fragrances, no harmful petrochemicals
- Contain Sodium Fluoride 0.225% (0.122% w/v fluoride ion)
- Vegan

Produced for and marketed by: K&Care Organics Ltd. Manufactured by: Peer Pharm Ltd., 17 Arnal St., Afek Ind. Zore, Rosh-Ha'Ayin, Israel

WWW.BOTAOBABY.COM



BOTAÓ

GROW NATURALLY

Kids Strawberry Flavored Toothpaste

Anticavity with fluoride

Maximum Cavity Protection Helps to maintain and protect teeth and gums

Enriched with Chamomile, Calendula and Aloe Vera

No Parabens No Sulfates

No artificial flavor, dyes or fragrances

1.69 FL OZ (50 mL)



BOTAÓ GROW NATURALLY

We, at BOTAO, believe that the natural way is the best way to grow and develop. Therefore, we insist on quality products that contain natural ingredients, and combine effective results with delicate textures.

BOTAO Toothpaste protects & cares for bables' teeth with a strawberry flavor loved by children. Made from delicate botanicals and ingredients, the non-abrasive formula cleanses teeth & gums, without harming the enamel. Contains soothing Chamomille, Calendula and Aloe Vera to sooth uncomfortable gums.

BOTAO KIDS STRAWBERRY FLAVORED WITH FLUORIDE

botao kids strawberry flavored toothpaste with fluoride paste

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69435-1405 Route of Administration DENTAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 0.122 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
XYLITOL (UNII: VCQ006KQ1E)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		

XANTHAN GUM (UNII: TTV12P4NEE)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CHAMOMILE (UNII: FGL3685T2X)	
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69435- 1405-1	1 in 1 CARTON	12/19/2022		
1		75 mL 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 final	part355	12/19/2022		

Labeler - Peer Pharm Ltd. (514678390)

Registrant - Peer Pharm Ltd. (514678390)

Establishment				
Name	Address	ID/FEI	Business Operations	
Peer Pharm Ltd.		514678390	manufacture(69435-1405)	

Revised: 3/2023 Peer Pharm Ltd.