

**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

- 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

Inactive Ingredients

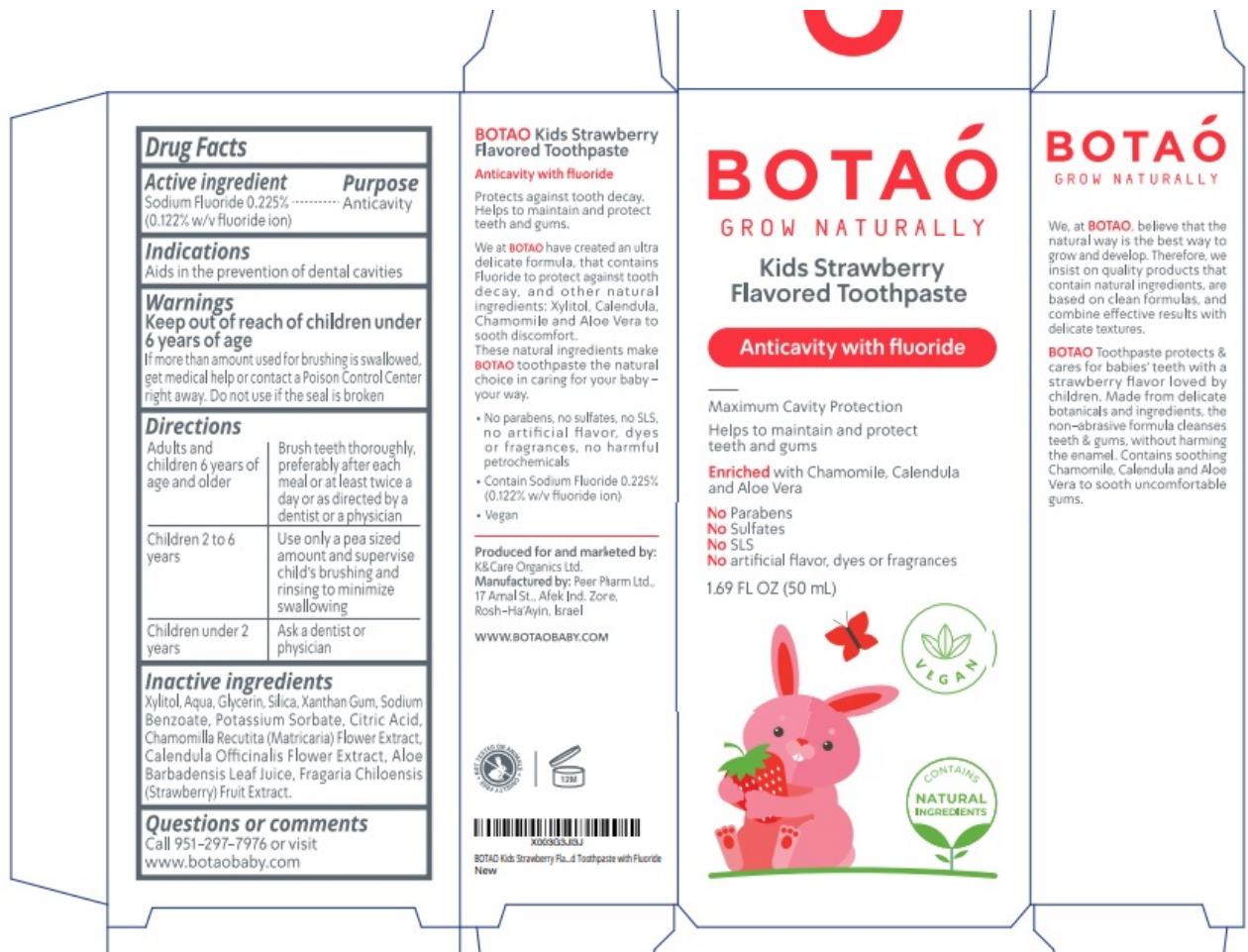
Aqua, Glyceryl Stearate SE, Cetyl Alcohol, Butyrospermum Parkii (Shea) Butter, Ricinus Communis (Castor) Seed Oil, Glycerin, Microcrystalline Cellulose, Caprylhydroxamic Acid, Xanthan Gum, Caprylyl Glycol, Bisabolol, Propanediol, Sodium Phytate, Chamomilla Recutita (Matricaria) Flower Extract, Calendula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

Questions or comments

Call 951-297-7976 or visit

www.botaobaby.com

Product label



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	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: P0M7O4Y7YD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

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.