

FRAICHE KIDS PASTE, BUBBLE GUM FLAVOR- sodium fluoride paste
True Marker Pharmaceuticals, Inc.

Drug Facts

Active Ingredient

0.24% w/w Sodium Fluoride

Purpose

Anti-cavity

Uses □

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children under 6 years of age. If more than the recommended amount of the paste used for brushing is accidentally swallowed, get medical help or contact the Poison Control Center right away. In case of an allergic reaction, stop use, rinse mouth with water and seek medical advice.

Directions

For adults and children 2 years of age or older, apply a small peasized amount of FRAICHE Kids dental gel to your toothbrush. For best results, brush for 2 minutes, expectorate and avoid eating or drinking for 30 minutes after brushing. Use twice daily. Replace cap after use.

For children under 2 years of age, consult a dentist or physician.

Other information

- Store at controlled room temperature, 68-77°F (20-25°C).
- Do not use if safety seal is broke or missing.

Inactive Ingredients

Pure Water, Glycerol, Sorbitol, CMC-NA, Propylene Glycol, Silicon Dioxide, Titanium Dioxide, Xylitol, Phosphoric Acid, Flavoring, Sodium Saccharin, Ethyl P-hydroxybenzoate, Propyl P-hydroxybenzoate, Butyl P-hydroxybenzoate, Sodium-N-lauroyl Sarcosinate.

Questions or Comments?

Call 1-888-811-2634

www.truemarkpharma.com

Product label



NDC 83592-803-46

FRAICHE
KIDS PASTE 0.24% w/w Sodium Fluoride
Dental Gel for Children



FRAICHE
KIDS PASTE

0.24% w/w Sodium Fluoride
Dental Gel for Children

Clean & Protect

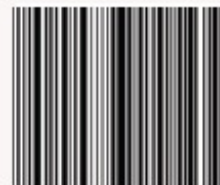
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BUBBLE GUM

Drug Facts

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Warning	
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Directions	
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Other Information	
Store away from direct sunlight and at room temperature, 8-25°C (46.4 - 77°F).	
Inactive Ingredients	
Pure Water, Glycerol, Sorbitol, CMC-NA, Propylene Glycol, Silicon Dioxide, Titanium Dioxide, Xylitol, Phosphoric Acid, Flavoring, Sodium Saccharin, Ethyl P-hydroxybenzoate, Propyl P-hydroxybenzoate, Butyl P-hydroxybenzoate, Sodium-N-lauroyl Sarcosinate.	
Questions or Comments?	
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Manufactured for: True Marker
Pharmaceuticals, Inc., Phoenix, AZ 85040



FRAICHE KIDS PASTE, BUBBLE GUM FLAVOR

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83592-803
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ETHYLPARABEN POTASSIUM (UNII: 528JBB2994)	
BUTYL SALICYLATE (UNII: QPR9LM8VZO)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83592-803-46	1 in 1 BOX	06/20/2024	
1		46 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 Drug	M021	06/20/2024	

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 6/2024

True Marker Pharmaceuticals, Inc.