

THOMAS AND FRIENDS- sodium fluoride paste, dentifrice
Ashtel Studios, Inc.

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.

Thomas & Friends Toothpaste

Drug Facts

Active Ingredients

Sodium Fluoride 0.243% (0.15% w/v Fluoride Ion)

Purpose

Anticavity Toothpaste

Uses

Helps protect teeth against cavities.

Warning

KEEP OUT OF REACH OF CHILDREN

If more than used for brushing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

Adults and children 6 years of age and older:

- Brush teeth thoroughly after meals or at least twice a day. Use directed by a dentist.
- Do not swallow.
- To minimize swallowing, use a pea-sized amount in children under 6 years of age.
- Supervise children's brushing until good brushing habit are established.
- Children under 2 years of age: Ask a dentist.

Inactive Ingredients

Sorbitol, Silica, Aqua, PEG-32, Xylitol, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Benzyl Alcohol, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, FD&C Blue #1, FD&C Red #40.

Other Information

Store at room temperature.

QUESTIONS? COMMENTS? / COMMENTAIRES?

1-877-274-8358 (U.S.A.)

1-909-434-0911 (INTERNATIONAL)

1-888-635-5337 (CANADA)

BUBBLE GUM GOMME À BULLES

ANTICAVITY FLUORIDE TOOTHPASTE DENTIFRICE ANTICARIE AU FLUORURE

make brushing fun!®

**For more oral care information,
visit us at / Pour d'autres
renseignements, visitez:
www.brushbuddies.com**

DISTR. BY/PAR NORTHERN NATIONAL
SALES INC. TORONTO, ON, M9M 1M7

C.No. DNH/COS/DNH/52

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Packaging

Brush Buddies
THOMAS & FRIENDS
TM/MD

BUBBLE GUM GOMME À BULLES

ALL ABOARD

Brush Buddies

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Brush Buddies For more oral care information, visit us at / Pour d'autres renseignements, visitez www.brushbuddies.com

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C.No. DNH/COS/DNH/52

ONTARIO, CA 91761
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THOMAS AND FRIENDS

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 108-015
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	243 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70 108-015-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/09/2018	

Labeler - Ashtel Studios, Inc. (148689180)

Revised: 5/2018

Ashtel Studios, Inc.