

**DENTEK LOONEY TUNES KIDS BUBBLEGUM BLAST- fluoride toothpaste paste, dentifrice
DenTek Oral Care, 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.

DenTek Looney Tunes Kids Anticavity Fluoride Toothpaste

Active Ingredients:

Sodium Fluoride 0.22% (0.126% w/v Fluoride Ion)

Purpose:

Anticavity

Use:

Helps protect against cavities

Warnings:

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

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

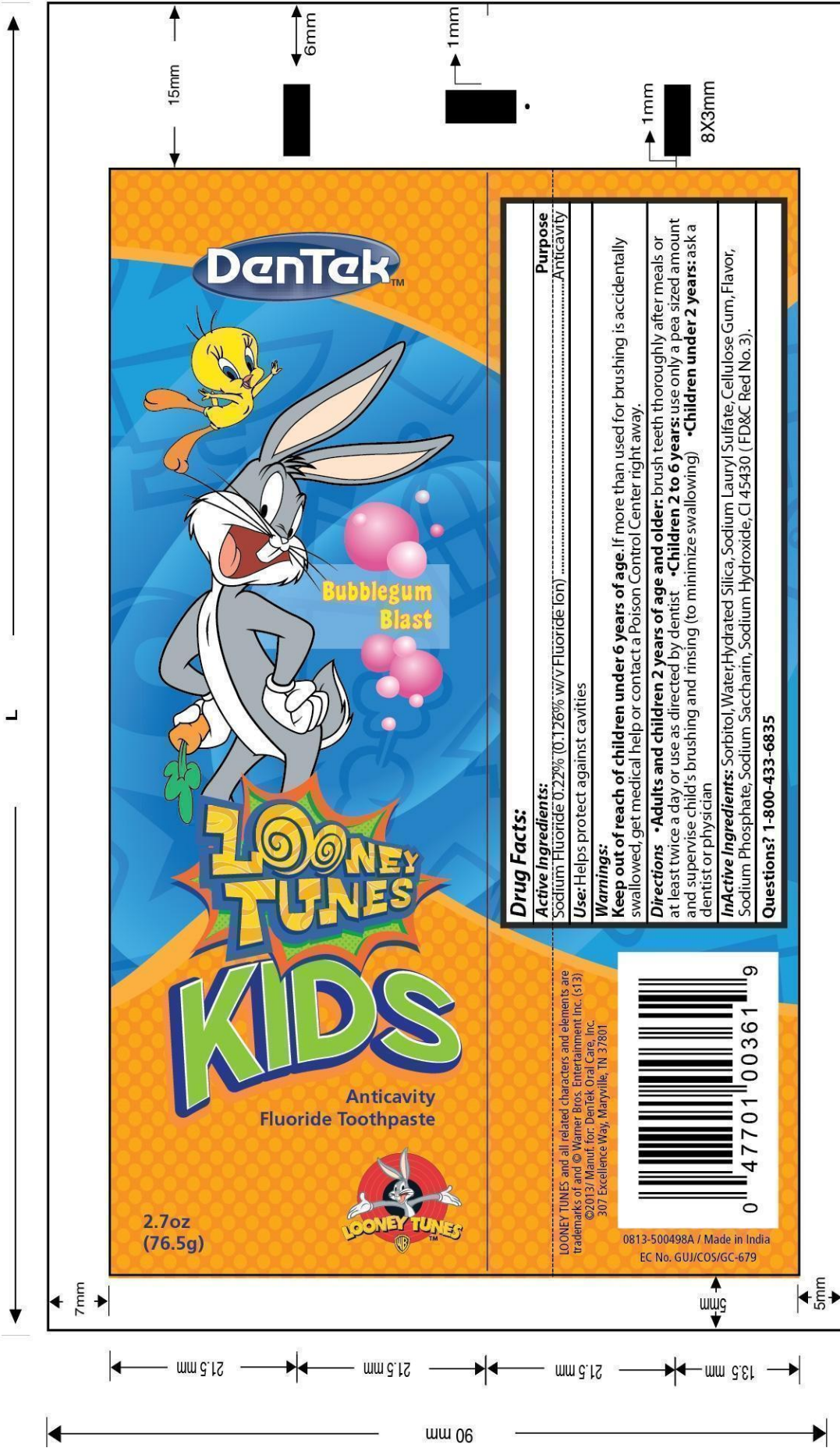
Directions: . **Adults and children 2 years of age and older:** brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist .**Children 2 to 6 years:** use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) .**Children under 2 years:** ask a dentist or physician

Inactive Ingredients: Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Phosphate, Sodium Saccharin, Sodium Hydroxide, CI 45430 (FD&C Red No. 3).

Questions? 1-800-433-6835

toothpaste tube label

LAYOUT FOR DIA 28 mm x 150mm
 L (Tube Length) = Final tube Length



DENTEK LOONEY TUNES KIDS BUBBLEGUM BLAST

fluoride toothpaste paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60630-498
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.09639 g in 76.5 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	61.1618 g in 76.5 g
HYDRATED SILICA (UNII: Y6O7T4G8P9)	15.3 g in 76.5 g
SODIUM PHOSPHATE (UNII: SE337SVY37)	0.3825 g in 76.5 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.176 g in 76.5 g
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	0.918 g in 76.5 g
ERYTHROSINE SODIUM ANHYDROUS (UNII: 8TL7LH93FM)	0.0008 g in 76.5 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	1.3005 g in 76.5 g
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.0765 g in 76.5 g
SORBITOL (UNII: 506T60A25R)	42.075 g in 76.5 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60630-498-01	76.5 g in 1 TUBE; Type 0: Not a Combination Product	02/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/28/2014	

Labeler - DenTek Oral Care, Inc. (153818646)

Registrant - DenTek Oral Care, Inc. (153818646)

Establishment

Name	Address	ID/FEI	Business Operations
DenTek Oral Care, Inc.		153818646	label(60630-498)

Establishment

Name	Address	ID/FEI	Business Operations
Goran Pharma Pvt. Ltd.		862174088	manufacture(60630-498)

Revised: 2/2016

DenTek Oral Care, Inc.