

SHOPKINS MOUTH WASH- sodium fluoride liquid
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.

Shopkins Mouth wash

Anticavity

Keep out of reach of children. In case of accidental digestion seek professional assistance or contact a poison control center immediately.

□Active Ingredient Purpose

Sodium Fluoride 0.5% (0.23% w/v fluoride ion) Anticavity

Helps protect teeth and roots against cavities

keep out of reach of children.

If you accidentally swallow seek medical help or contact a poison control center immediately

Water, Glycerine, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Xylitol, Benzyl Alcohol, Flavor, Sodium Benzoate, Sodium Saccharin, Zinc Gluconate, FD&C Red 40, D&C Red 33

Adults and children 6 years and older:

Use daily after your normal brushing. Rinse toothpaste from your mouth prior to use.

Rinse or gargle for 30 seconds with 15ml (3 teaspoonful) and then spit it out.

Do not swallow the mouth wash

Route of Administration	DENTAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
CITRAL PROPYLENE GLYCOL ACETAL (UNII: 9W7YHX7EX6)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR)	
WATER (UNII: 059QF0KO0R)	
.ALPHA-(.ALPHA.-AMINOPROPYL)BENZYL ALCOHOL HYDROCHLORIDE, ERYTHRO-(+/-) (UNII: 3IIJ9C722I)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	red (FD & C Red 33) , red (FD & C Red 40)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-008-01	479 g in 1 TUBE; Type 0: Not a Combination Product	10/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/06/2016	

Labeler - Ashtel Studios Inc. (148689180)

Establishment

Name	Address	ID/FEI	Business Operations
Dabur India Limited		650599231	manufacture(70108-008)