OLIDENTAL GARGLE- sodium fluoride liquid
AJU PHARM CO., 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

Sodium Fluoride 0.02%

Anticavity

Aids in the prevention of dental cavities

Adults and children 12 years of age and older:
• Use twice daily after brushing your teeth with a toothpaste
• Vigorously swish 10mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
• Do not swallow the rinse
• Do not eat or drink for 30 minutes after rinsing
• Supervise children as necessary until capable of suing without supervisor

Children under 12 years of age: consult a dentist or doctor

Stop use and ask a dentist if oral irritation or tooth sensitivity occurs

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Glycerin, Allantoin, Xylitol, Stevioside, Acetic acid, Sodium bicarbonate, Sodium acetate, Olive leaf extract, Sodium Benzoate, Green Tea Extract, Sodium Saccharin, L-Menthol, Citrus flavoring, Lemon flavoring, Propolis Extract, Lemon Oil, Cacao Color, Purified water

OLIDENTAL GARGLE

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70417-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.06 mg in 300 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
XYLITOL (UNII: VCQ006KQ1E)	
STEVIOSIDE (UNII: 0YON5MXJ9P)	
ACETIC ACID (UNII: Q40Q9N063P)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
LEMON OIL (UNII: I9GRO824LL)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70417-001-01	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2016	

Marketing Information

Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph final	part355	01/20/2016	

Labeler - AJU PHARM CO., LTD. (687982405)

Registrant - AJU PHARM CO., LTD. (687982405)

Establishment

Name	**Address**	**ID/FEI**	**Business Operations**
AJU PHARM CO., LTD.		687982405	manufacture(70417-001)