2080 K ORIGINAL- sodium fluoride paste
AK AMERICA

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.

Active Ingredient: Sodium Fluoride 0.22% (0.1% w/v fluoride)

Purpose: anticavity

Do not use this product for purposes other than those described on the label. In case of eye contact, rinse off immediately with water. If irritation persists, seek medical help.

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

Stop using this product and consult your dentist if irritation to gums, teeth, or oral mucosa occurs

Do not swallow. Rinse mouth with water after brushing.

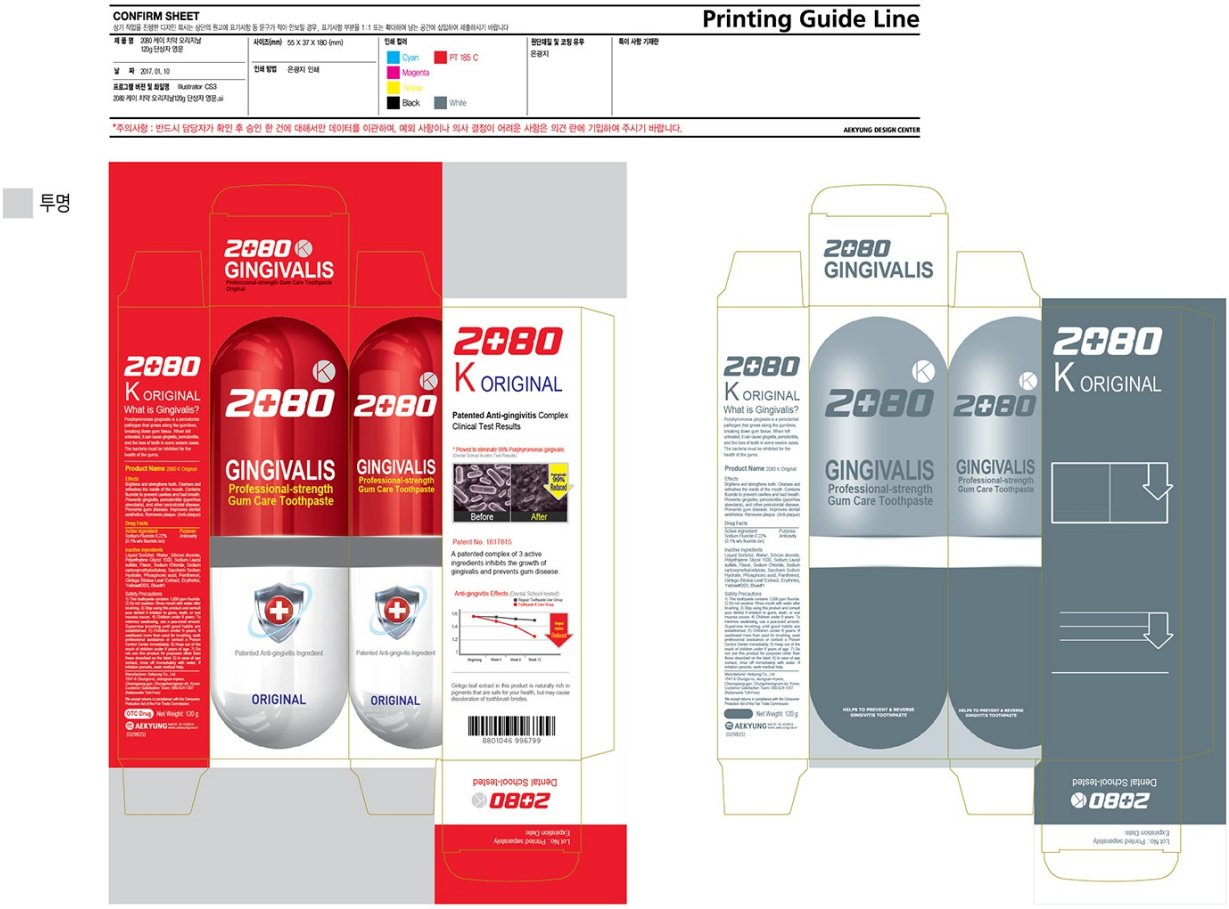
Children under 6 years:

- To minimize swallowing, use a pea-sized amount. Supervise brushing until good habits are established.

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

This toothpaste contains 1,000 ppm fluoride

Inactive Ingredients: Liquid Sorbitor, Water, Silicon Dioxide, Polyethylene Glycol 1500, Sodium Lauryl Sulfate Flavor, Sodium Chloride, Sodium Carboxymethylcellulose, Saccharin Sodium Hydrate, Phosphoric Acid, Panthenol, Ginkgo Biloba Leaf Extract, Erythritol, Yellow#203, Blue#1



2080 K ORIGINAL

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71401-0007
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	72 g in 120 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	3.12 g in 120 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.6 g in 120 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.156 g in 120 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.12 g in 120 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	22.8 g in 120 g
WATER (UNII: 059QF0KO0R)	12.07 g in 120 g

PANTHENOL (UNII: WV9CM0O67Z)	0.6 g in 120 g
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	0.006 g in 120 g
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.00156 g in 120 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GINKGO (UNII: 19FUJ2C58T)	
ERYTHRITOL (UNII: RA96B954X6)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71401-0007-1	1 in 1 PACKAGE	01/02/2017	
1		120 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 final	part355	01/02/2017	

Labeler - AK AMERICA (690064554)

Establishment

Name	Address	ID/FEI	Business Operations
AK AMERICA		690064554	relabel(71401-0007)

Establishment

Name	Address	ID/FEI	Business Operations
Aekyung Ind. Co., Ltd._Chungyang Factory		690511126	manufacture(71401-0007)

Revised: 4/2017 AK AMERICA