IODENT ANIMAL KINGDOM BUBBLE GUM- sodium fluoride paste United Exchange Corp.

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

Purpose

Sodium fluoride 0.22%------Anti-Cavity

(Available fluoride content:1000 ppm)

Uses

Aids in the prevention of dental 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 the reach of children under 6 years of age.

Direction:

Aduts and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Children under 6 years: Instruct children under 6 years of age to use a pea size amount. Supervise child's brushing and rinsing (to minimize swallowing).

Children under 2 years of age: Consult a dentist or physician.

Inactive ingredients

water, sorbitol, silica, polyethylene glycol 400, sodium carboxymethylcellulose, sodium lauryl alcohol, gum flavor, titanium dioxide, sodium saccharin, methylparaben, propylparaben, color: pink

Distributed by:

United Exchange Corp.

17211 Valley View Ave.,

Cerritos, CA 90703 USA



IODENT ANIMAL KINGDOM BUBBLE GUM

sodium fluoride paste

Product	Information	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:65923-106

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
METHYLPARABEN (UNII: A218 C7HI9 T)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65923-106-85	1 in 1 CARTON				
1		85 g in 1 TUBE				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part355	06/13/2014				

Labeler - United Exchange Corp. (840130579)

Revised: 3/2015 United Exchange Corp.