AQUAWHITE RED GEL CAVITY FIGHTINGTOOTH- sodium monofluorophosphate paste, dentifrice
JHS SVENDGAARD LABORATORIES LIMITED

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 Monofluorophosphate 0.76%

Purpose:

Anticavity

Uses:

Helps protect against cavities

Warnings:

If you accidentally swallow more than used for brushing, seek professional help

Keep out of reach of children under 6 years of age

Directions:

- Adults and children 2 years and older:
- Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- Do not swallow
- Children under 6 Years of Age

- To minimize swallowing use a pea-sized amount and supervise children's brushing untill good habits are established.

Children under 2 years of age:

- Ask a dentist or physician

Inactive Ingredients:

Sorbitor, Water, Silica, Glycerin, Sodium Lauryl Suphate, Flavor, PEG-1500, Sodium Carboxymethylcellulose, Xylitol, Xanthan Gum, Sodium Methyl Paraben, Sodium Phosphate, Sodium Propyl Paraben, Sodium Saccharin, Cooling Crystal, FD&C Red 40

AQUAWHITE RED GEL CAVITY FIGHTINGTOOTH

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72025-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL (UNII: L7T10EIP3A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

SODIUM PHOSPHATE (UNII: SE337SVY37)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72025-003-01	80 g in 1 TUBE; Type 0: Not a Combination Product	01/16/2018	
2	NDC:72025-003-02	150 g in 1 TUBE; Type 0: Not a Combination Product	01/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/16/2018	

Labeler - JHS SVENDGAARD LABORATORIES LIMITED (675939900)

Establishment

Name	Address	ID/FEI	Business Operations
JHS SVENDGAARD LABORATORIES LIMITED		675939900	manufacture(72025-003)

Revised: 1/2018 JHS SVENDGAARD LABORATORIES LIMITED