

AQUAWHITE BLUE 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 until good habits are established.

Children under 2 years of age:

- Ask a dentist or physician

Inactive Ingredients:

Sorbitol, Water, Silica, Glycerin, Sodium Lauryl Sulfate, Flavor, PEG-1500, Sodium Carboxymethylcellulose, Xylitol, Xanthan Gum, Sodium Methyl Paraben, Sodium Phosphate, Sodium Propyl Paraben, Sodium Saccharin, Cooling Crystal, FD&C Blue 1



AQUAWHITE BLUE GEL CAVITY FIGHTING TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72025-002
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
SODIUM PHOSPHATE (UNII: SE3375VY37)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0K00R)	
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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72025-002-01	80 g in 1 TUBE; Type 0: Not a Combination Product	01/16/2018	
2	NDC:72025-002-02	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(72025-002)

Revised: 1/2018

JHS SVENDGAARD LABORATORIES LIMITED