

TECHNICAL DATA SHEET

Product: Alpha-Dent® Home Care Fluoride Gel

Product Description: Alpha-Dent® Home Care Fluoride Gel is the ideal product for patients suffering from sensitivity caused from tooth whitening procedures. It provides the benefits of stannous fluoride: inhibits plaque growth, helps eliminate hypersensitivity, and aids in the prevention of dental caries. It also reduces the possibility of de-calcification and band marks for orthodontic patients. The gel is available in four flavors.

Indications for Use: Alpha-Dent® Home Care Fluoride Gel is a fluoride treatment gel intended for home use by simply applying the gel to your teeth by brushing. Allow it to remain for 1 minute and then spit out.

Appearance: Clear, colorless to pale yellow flowing gel.

Curing Mechanism: Not applicable.

Shelf-Life: 36 months

Filler Type: None

Main Composition (%w/w):

Inactive Ingredients:

Humectant	96 – 98
Thickener	< 5
Buffering Agent	< 1
Antioxidant	< 1
Flavoring	< 1

Active Ingredient:

Stannous Fluoride, USP	0.40
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Physical /Mechanical Properties: (Typical Values)

Depth of Cure, mm (actual)	6.0
% Free Fluoride as Stannous Fluoride	0.40
% Stannous Ion per % Stannous Fluoride,	75.00
% Stannous Ion per % Total Tin,	100.00
Viscosity, cP @ 25 °C,	27,000
pH (1:1 Aqueous Solution)	3.30
Specific Gravity	1.27

Regulatory Classification:

This product is in conformity with the following standard(s) or other normative documents:

Code of Federal Regulations 21 CFR 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
Code of Federal regulations 21 CFR 355.10 – Anti Caries Drug Product for Over-The-Counter Human Use
Current USP