

FluoroDose[®]

5% Sodium Fluoride Varnish with Xylitol

Applying FluoroDose 5% Sodium Fluoride varnish is an effective step of an overall comprehensive oral care and prevention program. From time to time, questions are asked about the composition of the FluoroDose material and the concern for allergic reactions.

Besides the 5% sodium fluoride, FluoroDose also contains processed pine rosin, or colophony, the sticky sap from conifer trees. Rosin or colophony has a wide application in many industries, including pharmaceuticals, because of its properties to stick to other substances. It is a major ingredient in the FluoroDose formulation for that reason as it can block dentin tubules to treat tooth sensitivity conditions and remain on the tooth for the period of time needed for the sodium fluoride ingredient to release as well.

Allergic reactions to rosin or colophony are known to the medical community, and our instructions specifically advise the health care professional of this risk.

The application of any sodium fluoride varnish, including FluoroDose, should take into consideration a patient's tolerance to this material in consideration of their health history. The FluoroDose instructions, as previously noted, contra-indicate for patients with a known colophony allergy but also sodium fluoride as well. FluoroDose also contains beeswax and FD&C Red Dye 40 which may affect the decision to use this product.

Equally important is providing information on common allergens which are not present in the FluoroDose formulation and this information is given in the chart below:

ALLERGEN:	PRESENT IN FluoroDose
Dairy Products (including derivatives)	NO ¹
Egg Products	NO ¹
Gluten (Including wheat, barley, millet & rye)	NO ¹
Soy Products (Including soy lechithin)	NO ¹
Peanut Products	NO ¹
Tree Nuts & Derivatives (Including almond, brazil nut, cashew, chestnut, hazelnut (filbert), macadamia nut, pecan, pine nuts, pistachio, walnut)	NO ¹
Seed Products (Including sesame, sunflower, cottonseed, poppy)	NO ¹

Recently, it has been brought to our attention that there is some confusion between pine rosin and pine nut allergies. As indicated above, pine rosin (colophony) and pine nuts are known allergens, each with their own presentation of symptoms and treatments. Following a thorough scientific literature review, we do not find any evidence to suggest that having allergies to pine nuts automatically makes the patient allergic to pine rosin. The suspected allergens in pine nuts are different than those in pine rosin because the chemical composition of each is different from the other, and the sources from where each originates is also different.

Our objective at Centrix is to provide as much safety information as possible regarding the use of our products through the use of cautions and contra-indications found in our instructions. In those cases where we are unable to provide specific warnings for specific ingredients, we strongly encourage that an allergen patch screening test be performed using our material to make the best judgement for the patient.



Greg Moreau, Director, QA & Regulatory Affairs

¹Although there are no allergens present in the product itself, the above allergens may be present in the same facility and/or manufacturing equipment used to produce the raw materials and/or finished product.