February 23, 2015

Dear Healthcare Professional,

NUPRO® 5% Sodium Fluoride Varnish contains a component, hydrogenated pine rosin, which is originally derived from pine oil. Because some patients have allergies to pine nuts, there is concern that using NUPRO® 5% Sodium Fluoride Varnish could cause an allergic reaction. There is also concern that a patient with an allergy to other tree nuts or peanuts could have a reaction to the varnish.

DENTSPLY commissioned an independent third party, NAMSA Product Safety and Validation, to review and evaluate the medical and scientific literature and provide a toxicological overview of pine rosin and rosin derivatives. Specific focus was given to the allergic potential of the hydrogenated pine rosin contained in NUPRO® 5% Sodium Fluoride Varnish. The suspected allergens in pine nuts are different from those in rosin because the chemical composition and pine tree sources are not the same. Based on the scientific literature and because the suspected allergens are different, it is unlikely that the severe allergic reactions seen with consumed pine nuts would be seen with products that contain rosin or its derivatives.

NUPRO® 5% Sodium Fluoride Varnish has been thoroughly assessed for biocompatibility and has been successfully used in millions of patients. Based on the information above, NUPRO® 5% Sodium Fluoride Varnish remains safe for its intended use.

Thank you for choosing NUPRO® 5% Sodium Fluoride Varnish.

Eliane Schaeffer
Quality & Regulatory Affairs Director