PerioMed™

0.63% Stannous Fluoride Oral Care Rinse

DESCRIPTION: A stable, water free suspension of 0.63% stannous fluoride for dilution to 0.1% stannous fluoride for use as an oral rinse. A 30 ml. dose yields 7.0 mg fluoride ion and 22 mg stannous ion.

ACTIVE INGREDIENT: Stannous Fluoride 0.63% (Wt/Wt).

CLINICAL PHARMACOLOGY: It is well established that stannous fluoride is antimicrobial, promotes remineralization, and increases tooth resistance to acid dissolution when delivered in adequate, stable concentrations.

INDICATIONS: Label indications of dental caries prevention, severe hypersensitivity and control of ainaival inflammation.

CONTRAINDICATIONS: None

WARNINGS: Product may produce temporary surface staining of teeth. Xerostomia, mouth breathers, and other conditions where soliva flow is reduced are more susceptible. Adequate brushing may control these stains, which are not permanent and can be removed by vour dental professional.

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Keep this, and all other medications out of the reach of children. Dilute with water per label directions prior to use. Pediatric patients (12 years old and under) require supervision in use of all prescription rinse products to avoid ingestion. Consult your dentist or physician for use by pediatric patients under 6 years old.

PRECAUTIONS: DO NOT SWALLOW. Instruct children under 12 years of age in proper rinsing habits (to minimize swallowing). Supervise children until capable of rinsing without supervision. For use by children under 6 years of age: Consult a dentist or physician.

OVERDOSAGE: Accidental ingestion of individual dosage (ie: 1/8 oz. of PerioMed concentrate) is not harmful. If swallowed and nausea or vomiting occurs, treat with milk or antacids.

DOSAGE AND ADMINISTRATION:

- 1. Use once daily or as directed by your dentist.
- Make two (2) complete pump depressions into cup provided (1/8 oz.). Add water to top line on cup.
 This prepares a 0.1% stannous fluoride rinse.
- 3. Mix using bristle end of toothbrush.
- Place 1/2 of the solution into your mouth. Swish for one (1) minute. Expectorate (spit).
 Repeat the one (1) minute treatment with the remaining solution. Expectorate (spit).
- **DOSAGE AND ADMINISTRATION FOR HOME IRRIGATORS:** Prepare 1 oz. of PerioMed™ Oral Rinse as described in the Dosage and Administration section. Pour into irrigator reservoir and add four (4) ounces of water. Mix thoroughly. This prepares a 0.02% stannous fluoride irrigant. Use irrigator per manufacturer's directions. Rinse irrigator with water rifter each use

HOW SUPPLIED: Mint, Tropical Fruit, and Cinnamon flavors in 10 oz. bottles with pump dispenser.

Rx only.

Manufactured by: OMNII Oral Pharmaceuticals 1500 North Florida Mango Rd West Palm Beach, FL 33409 Revised July 2004