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Description

PRODUCT IDENTIFIER: In Office Rinse (2 part rinse) containing a concentrate of 1.24% fluoride ion from sodium fluoride in 0.1 molar phosphate at pH 4.0. May contain FD&C Red #40, FD&C Yellow #5, FD&C Blue #1. Stannous Product is a stable water-free concentrate containing 1.64% stannous fluoride.

PRODUCT IDENTIFICATION NUMBER: FL-OFC-R-

PRODUCT USE: For professional use to aid in the prevention of dental caries.

PRODUCT MANUFACTURER: Ross Chempharma Inc. EMERGENCY TELEPHONE NO.: 1-800-663-8303

Indications and Usage

For Topical application to aid in the prevention of dental caries.

Active Ingredients

Part A: Fluoride Ion (from sodium fluoride) CAS# 7681-49-4 1.24%

Colors: Red 40 CAS #25956-17-6, Yellow 5 CAS#1934-21-0, Blue 1 CAS#3844-45-9, see

table below

Part B: Stannous Fluoride CAS# 7783-47-3 1.64%

Contraindications

None.

Warnings

Keep out of reach of children. For professional use only. Do not swallow. Use with caution on patients with porcelain or ceramic restorations as per "Precautions."

Precautions

Repeated use may cause dulling of porcelain of ceramic dental work.

Adverse Reaction

Ingestion may produce nausea and/or vomiting. Contact with sensitive gingival tissue may produce discomfort.

First Aid Measures

Ingestion: If treatment dose swallowed (≤ 100 mg F) drink mild or calcium-type antacid. If larger dose drink with Ipecac Syrup and seek medical attention immediately.

GENERAL TREATMENT DIRECTIONS

The following treatment method produces high initial protection levels on tooth surfaces.

TWO MINUTE COMBINED RINSE METHOD:

• One-Minute Rinses of the combined APF (Acidulated Phosphate Fluoride), and SnF₂ (Stannous Fluoride) Solution.

Combined Rinse is prepared by placing 7.5ml (1/4oz) of APF (Acidulated Phosphate Fluoride) [dispensed with one pump], and 7.5ml (1/4oz) of SnF₂ (Stannous Fluoride) [dispensed with one pump], in a calibrated mixing cup with 22.5 ml (3/4oz) of water.

CONSIDERATIONS FOR THE TREATMENT OF ADULTS: After treatment sequences, have patient expectorate five times at about five-second intervals to clear the mouth of any excess or remaining solution. Instruct patient not to eat or drink for 30 minutes.

SPECIAL CONSIDERATIONS FOR THE TREATMENT OF CHILDREN: Prepare the solution in the usual manner, the put half of the solution in second cup (produces about 15ml in each cup). Before starting, give the child a small amount of mouthwash and have the child swish it around in their mouth using tongue and cheek muscles, WITHOUT SWALLOWING. After you are sure the child can follow

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your instructions, have the child expectorate several times to clear their mouth thoroughly. Confirm child has not swallowed. CONTINUE ONLY IF YOU ARE SURE CHILD WILL FOLLOW INSTRUCTIONS WITHOUT SWALLOWING. Have the child take half of the contents of the first cup and switch it around their mouth for 30 seconds, then expectorate repeat procedure with the second half of mixture. Repeat procedure with dosage in second cup. After treatment, have child expectorate several times to clear mouth of any excess solution.

Caution

US FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. Keep out of reach of children.

Storage

Store at room temperature. Do not freeze

MSDS SUPPLEMENT, COLOR ADDITIVES

_	RED#40	BLUE 1	YELLOW#5
STRAWBERRY	X	X	
COOL PEPPERMINT		X	
BUBBLEGUM	X		
GRAPE	X	Х	
LUSCIOUS LIME		X	X

UPDATED: 1/1/2011