

MEDACTIVE PATIENT FRIENDLY- stannous fluoride Integrate Oral Care, LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Stannous fluoride 0.1%

Purpose

Cavity protection

Uses

- Aids in the prevention of dental decay.
- When using this product, do not use longer than four weeks unless recommended by a medical doctor and/or dental professional.
- If more than used for rinsing is swallowed, seek medical attention or contact a Poison Control Center immediately.

Directions

Use immediately after preparing the rinse as follows:

Adults and children 6 years or age and older:

- Place both thumbs on **Blue Chamber No. 1** and Press down firmly to squeeze fluoride into **Chamber No. 2**.
- Gently Shake.
- Snap Tab to Open by bending at line on the cap. Dispense half of mixture into the mouth and Rinse for 30 seconds. Spit.
- Gargle with remainder of mixture for 30 seconds. Spit.
- Avoid any food or drinks for at least 15 minutes after use.

Children under 6 years of age:

- Consult your medical doctor and/or dental professional.

Other information

- This product may produce surface staining of the teeth.
- Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dental professional.
- Do not refrigerate. Store at room temperature.
- See Rinse or box for expiration date.

Inactive Ingredients

dimethicone, EDTA, FD&C Green No. 3, flavor (includes Spilanthes Extract), glycerin, poloxamer 407, potassium sorbate, sodium saccharin, sorbitol, sucralose, water

Questions or comments?

1-866-877-4876 M-F 9am-5pm EST or www.integrateoralcare.com

Keep out of reach of children.



MedActive® Oral Care Redefined™

Patient-Friendly™ Orange Crème

Stannous Fluoride Rinse with **ULTRAMULSION®** & **Spilanthes Extract**

10 DOSE PACKS

IMPORTANT

Read directions for proper use.

NET CONTENTS: 10 DOSE PACKS 10.4 FL OZ (307 mL)

NDC 49741-1005-2

MedActive® Oral Care Redefined™

Patient-Friendly™ Orange Crème

Stannous Fluoride Rinse with **ULTRAMULSION®** & **Spilanthes Extract**

30 DOSE PACKS

IMPORTANT

Read directions for proper use.

NET CONTENTS: 30 DOSE PACKS 31.2 FL OZ (923 mL)

NDC 49741-1005-3



MEDACTIVE PATIENT FRIENDLY

stannous fluoride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49741-1005
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741-1005-2	10 in 1 BOX	07/31/2014	
1	NDC:49741-1005-1	1 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:49741-1005-3	30 in 1 BOX	07/31/2014	
2		1 in 1 CARTON; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 KIT	3.7 mL

Part 2 | 1 KIT

27 mL

Part 1 of 2**CHAMBER NO. 1**

stannous fluoride concentrate

Product Information**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	6.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 1 mL
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.7 mL in 1 KIT; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/31/2014	

Part 2 of 2**CHAMBER NO. 2**

stannous fluoride diluent emulsion

Product Information**Route of Administration** ORAL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETIC ACID (UNII: 9G34HU7RV0)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE (Orange Crème with ULTRAMULSION® and Spilanthes Extract)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		27 mL in 1 KIT; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/31/2014	

Labeler - Integrate Oral Care, LLC. (063540457)

Registrant - Integrate Oral Care, LLC. (063540457)