## OPTIRINSE PLUS- remineralizing fluoride rinse liquid Laboratoires MSP Inc

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.

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## **OptiRinse Plus**

## Active Ingredients (in 10 mL)

Cetylpyridinum Chloride 0.05%

Sodium Fluoride 0.05% (0.02% w/v fluoride ion)

## Purpose

Antigingivitis/antiplaque

Anticavity

#### Uses

- Aids in the prevention of dental cavities
- Helps prevent and reduce plaque and gingivitis
- Helps control plaque bacteria that contribute to the development of gingivitis and bleeding gums

## Warnings

- **Keep out of reach of children.** If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- Ask a dentist if symptoms persist or condition worsens after regular use.

#### **Directions**

Adults and children 6 years of age and older	<ul> <li>Use once a day after brushing your teeth with a toothpaste</li> <li>Remove cap</li> <li>Pour 10 milliliters into a cap (10 mL mark on inside of cap); do not fill above 10 mL mark</li> <li>Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out</li> <li>Do not swallow the rinse</li> <li>Do not eat or drink for 30 minutes after rinsing</li> <li>Instruct children 12 years under age in good rinsing habits (to minimize swallowing)</li> <li>Supervise children as necessary until capable of using without supervision</li> </ul>
Children under 6 years of age	Consult a dentist or doctor

#### Other Information

- Store at room temperature (15-30°C)
- Do not use if safety seal is broken or missing

## **Inactive Ingredients**

Purified Water, Xylitol, Glycerin, Grape Flavor, Poloxamer 407, Bioflavonoids, Sodium Phosphate, Benzoic Acid, Mint Flavor, Red 40

## OptiRinse Plus - Grape - 500 mL - NDC 77982-001-01



## OptiRinse Plus

Contains Citrox patented formula

Natural Bioflavinoid Complex

Ideal for Adults & children

00.05% NAF Remineralizing Fluoride Rinse

Grape Flavor

16.9 fl oz (500 ml)

Recommended by Dental Professionals

- Anti-cavities
- Anti-gingivitis
- 10% Xylitol
- Alcohol free
- Kills bacteria
- Lightly flavored
- Neutral pH

Questions? 1 888 442.7070 or boutique.oralscience.com

Distributed in USA by:

TruLife Distribution, 401 E Las Olas Blvd Suite 1400, Fort Lauderdale, Floirida USA 33301/954.414.0380

X-PUR is a registered trademark of Oral Science Inc.

## **OPTIRINSE PLUS**

remineralizing fluoride rinse liquid

<b>Product Information</b>
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77982-001
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Route of Administration DENTAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETYLPYRIDINIUM CHLORIDE (UNII: D9 O M4SK49 P) (CETYLPYRIDINIUM - UNII: CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.05 mg in 1 mL		
SODIUM FLUORIDE (UNII: 8 ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.05 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
XYLITOL (UNII: VCQ006KQ1E)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYL ANTHRANILATE (UNII: 981I0C1E5W)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)				
SO DIUM PHO SPHATE (UNII: SE337SVY37)				
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
PULEGONE (UNII: 4LF2673R3G)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	grape	Imprint Code		
Contains				

Pā	nckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77982-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2020	

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/04/2020	

# Labeler - Laboratoires MSP Inc (251046124)

Establishment				
Name	Address	ID/FEI	Business Operations	
Laboratoires MSP Inc		251046124	manufacture(77982-001)	

Revised: 11/2020 Laboratoires MSP Inc