

X-PUR OPTI-RINSE PLUS- anticavity fluoride rinse mouthwash
Oral Science 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.

Oral Science-Laboratoires MSP- X-Pur Mint Mouthwash

Active Ingredient(s)

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

Purpose

Anticavity

Use

aids in the prevention of dental cavities.

Warnings

Keep out of the reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Stop use and ask a doctor or dentist if symptoms persist or condition worsens after regular use

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If more than used for rinsing is accidently swallowed, get medical help or contact a Poison Control Center right away

Directions

- **Adults and children 6 years and older:**

Use once a day after brushing your teeth with a toothpaste

Remove cap

Pour 10 milliliters into a cap (10 mL mark on the inside of cap); do not fill above 10 mL mark Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out

Do not swallow the rinse

Do not eat or drink for 30 minutes after rinsing

Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing)

Supervise children as necessary until capable of using without supervision

- **Children 6 years and under**

Consult a dentist or doctor

Inactive ingredients

water, xylitol, glycerin, poloxamer 407, sodium phosphate, bioflavonoids, benzoic acid, cetylpyridinium chloride, mint flavor, blue 1

store at room temperature (59-86°F) do not use if safety seal is broken or missing

Package Label - Principal Display Panel

CONTAINS CITROX® PATENTED FORMULA

NATURAL BIOFLAVONOID COMPLEX

RECOMMENDED BY DENTAL PROFESSIONALS

- ✓ Anticavity
- ✓ Cleans teeth & gums
- ✓ Strengthens enamel
- ✓ 10% Xylitol
- ✓ Freshens breath
- ✓ Alcohol free
- ✓ Lightly flavored
- ✓ Neutral pH

0.05%^{NAF} ANTICAVITY FLUORIDE RINSE

Mint Flavor
16.9 fl oz (500 ml)

oral science
CREATING SYNERGIES

Questions? 1 888 442 7070 or oralscience.com

Distributor: Oral Science Inc. 9575-C Rue Ignace, Brossard, QC J4Y 2P3, CA 1 888 442 7070

Manufacturer: Laboratoires MSP Inc. 2401 Montée de Picardie, Varennes, QC J3X 0J1, Canada

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EXP
LOT

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500 mL NDC: 81359-114-11

X-PUR OPTI-RINSE PLUS

anticavity fluoride rinse mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81359-114
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION -	SODIUM FLUORIDE	0.05 g in 100 ml

UNII:Q80VPU4080)	SODIUM FLUORIDE	0.05 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
XYLITOL (UNII: VCQ006KQ1E)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
MINT (UNII: FV98Z8GITP)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81359-114-11	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/18/2021	

Labeler - Oral Science Inc (200633202)

Revised: 10/2022

Oral Science Inc