

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- 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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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

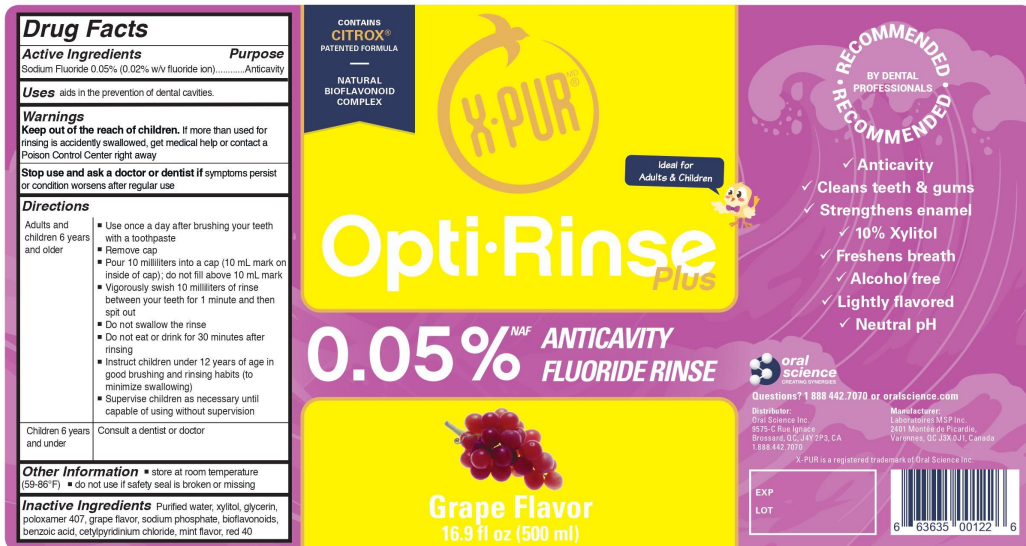
water, xylitol, glycerin, poloxamer 407, grape flavor, sodium phosphate, bioflavonoids, benzoic acid, cetylpyridinium chloride, mint flavor, red 40

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

Package Label - Principal Display Panel

0.05% - Grape

Date	Département	Signature
	Marketing	
	Assurance Qualité	



CYMK YELLOW
TRANSPARENT



GOLD
FOIL



4-COLOR PROCESS
METALIC

C: 30
Y: 78
M: 0
K: 0

C: 27
Y: 75
M: 0
K: 0

C: 25
Y: 70
M: 0
K: 0

C: 23
Y: 63
M: 0
K: 0

C: 22
Y: 61
M: 0
K: 0

C: 21
Y: 55
M: 0
K: 0

534 C



500 mL NDC: 81359-112-11

X-PUR OPTI-RINSE PLUS

anticavity fluoride rinse mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81359-112	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)		SODIUM FLUORIDE	0.05 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
XYLITOL (UNII: VCQ006KQ1E)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
GRAPE (UNII: 6X543N684K)				
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:81359-112-11	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355		02/04/2021	

Labeler - Oral Science Inc (200633202)

Revised: 10/2022

Oral Science Inc