

**FIREFLY ANTICAVITY FLUORIDE- sodium fluoride rinse**  
**Ranir 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.*

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**FIREFLY Anticavity Fluoride Rinse Toy Story Drug Facts**

**Active ingredient**

Sodium fluoride 0.05%

**Purpose**

Anticavity rinse

**Use**

aids in the prevention of dental cavities.

**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.

**Directions**

Adults and children 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste
- 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 rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor.

**Other information**

- recommended storage temperature 59°-86°F(15°-30°C)
- do not use if printed plastic neckband is broken or missing

## **Inactive Ingredients**

cetylpyridinium chloride, citric acid, D&C red #33, disodium EDTA, disodium phosphate, FD&C blue#1, flavor, PEG-40, hydrogenated castor oil, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium phosphate, sorbitol, sucralose, xylitol

## **Questions?**

Toll Free: **1-866-373-7374**

## **Principal Display Panel**

FIREFLY™ ANTICAVITY Fluoride Rinse

Disney PIXAR

TOY STORY

BUBBLE BERRY™

Helps PREVENT CAVITIES

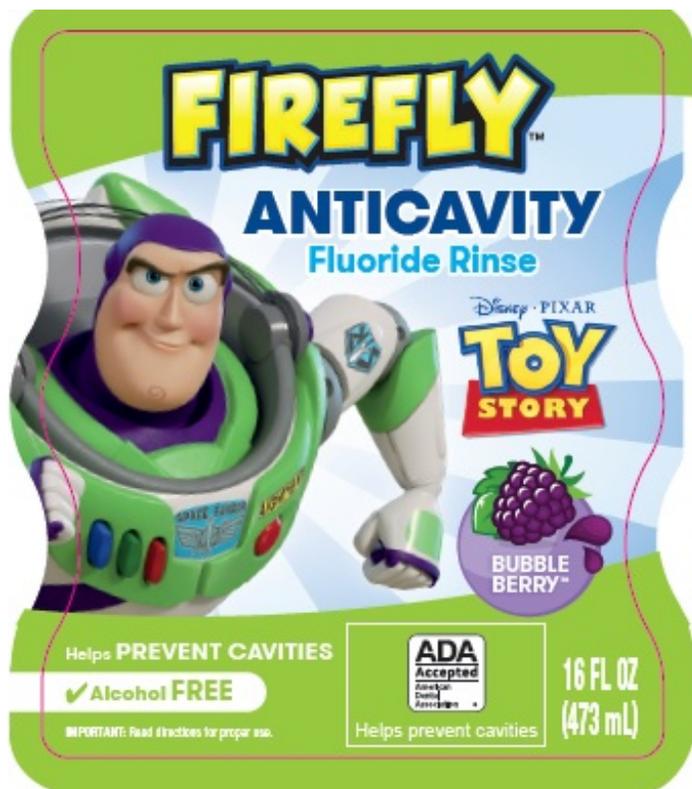
ADA Accepted American Dental Association

Helps prevent cavities

Alcohol FREE

IMPORTANT: Read directions for proper use.

16 FL OZ (473 mL)



Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Sodium fluoride 0.05%	Anticavity rinse
<b>Use</b> aids in the prevention of dental cavities.	
<b>Warnings</b> 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.	
<b>Directions</b> Adults and children 6 years of age and older: <ul style="list-style-type: none"> <li>■ use once a day after brushing your teeth with a toothpaste</li> <li>■ vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. ■ DO NOT SWALLOW THE RINSE</li> <li>■ do not eat or drink for 30 minutes after rinsing</li> <li>■ instruct children under 12 years of 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.	
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<b>Questions?</b> Toll Free: 1-866-373-7374	
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## FIREFLY ANTICAVITY FLUORIDE

sodium fluoride rinse

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:66923-111

Route of Administration DENTAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66923-111-43	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/15/2021	

Labeler - Ranir LLC (364567615)

