

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

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**FIREFLY Anticavity Fluoride Rinse Paw Patrol 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, disodium EDTA, disodium phosphate, FD&C blue#1, flavor, menthol, poloxamer 407, polysorbate 80, 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

PAW PATROL™

BUBBLE GUM

nickelodeon™

Helps PREVENT CAVITIES

ADA Accepted American Dental Association

Helps prevent cavities

Alcohol FREE

IMPORTANT: Read directions for proper use.

16 FL OZ (473 mL)

# FIREFLY™

## ANTICAVITY

### Fluoride Rinse



**nickelodeon.**

Helps **PREVENT CAVITIES**

✓ **Alcohol FREE**

IMPORTANT: Read directions for proper use.



Helps prevent cavities

**16 FL OZ**  
**(473 mL)**

### Drug Facts

| Active ingredient     | Purpose          |
|-----------------------|------------------|
| Sodium fluoride 0.05% | 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 8 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 8 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, disodium EDTA, disodium phosphate, FD&C blue #1, flavor, menthol, poloxamer 407, polysorbate 80, propylene glycol, purified water, sodium benzoate, sodium phosphate, sorbitol, sucralose, xylitol

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

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## FIREFLY ANTICAVITY FLUORIDE

sodium fluoride rinse

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:66923-003 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| <b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM45K49P)   |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)    |          |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM) |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)        |          |
| <b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)  |          |
| <b>POLOXAMER 407</b> (UNII: TUF21VW3M2)              |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)             |          |

|  |  |
|--|--|
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) |  |
| <b>WATER</b> (UNII: 059QF0KO0R)            |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)  |  |
| <b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37) |  |
| <b>SORBITOL</b> (UNII: 506T60A25R)         |  |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)        |  |
| <b>XYLITOL</b> (UNII: VCQ006KQ1E)          |  |

### Product Characteristics

|                 |            |                     |  |
|-----------------|------------|---------------------|--|
| <b>Color</b>    |            | <b>Score</b>        |  |
| <b>Shape</b>    |            | <b>Size</b>         |  |
| <b>Flavor</b>   | BUBBLE GUM | <b>Imprint Code</b> |  |
| <b>Contains</b> |            |                     |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:66923-003-43 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/16/2021           |                    |
| 2 | NDC:66923-003-34 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 11/05/2021           | 08/23/2023         |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M008                                     | 06/16/2021           |                    |

**Labeler** - Ranir LLC (364567615)