

PCXX APF RNS BUBBLEGUM- sodium fluoride rinse
Ross Healthcare Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

PCXX APF RNS BUBBLEGUM

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minute

| PCXX APF RNS BUBBLEGUM | | | |
|--|---|---------------------------|-----------------|
| sodium fluoride rinse | | | |
| Product Information | | | |
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:62007-319 |
| Route of Administration | TOPICAL, DENTAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 27.2 mg in 1 mL |

Product Characteristics

| | | | |
|-----------------|------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62007-319-64 | 1900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/11/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 06/11/2019 | |

Labeler - Ross Healthcare Inc. (064974821)

Revised: 1/2021

Ross Healthcare Inc.