

**ORABRITE - sodium fluoride paste, dentifrice**  
**Oraline, 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.*

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**Active Ingredient**

**DRUG FACTS**

**ACTIVE INGREDIENT:**

Sodium Fluoride 0.22%

(Total Fluoride Content - 1000 ppm approx.)

**Purpose**

PURPOSE: Anticavity Toothpaste.

**Keep Out Of Reach Of Children**

WARNINGS: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

**Use**

USE: Helps protect against cavities.

**Warnings**

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**Directions**

**DIRECTIONS:**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits. (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

**Inactive Ingredients**

**INACTIVE INGREDIENTS:**

Hydrated Silica, Sorbitol, Deionized Water, Methyl Paraben Sodium, Propyl Paraben Sodium, Sodium Lauryl Sulfate, Sodium Carboxymethylcellulose, Flavor, Sodium Saccharin.

**Package Label**

Distributed by Oraline Inc., 823 NYS RT 13, Cortland, N.Y. 13045

OraBrite

Mint Flavor with Fluoride

NET WT 1.50 oz.

Mfg. Date and Batch No. on crimp.

Product of China, produced for Oraline. 888-296-6730. www.oraline.net

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## ORABRITE

sodium fluoride paste, dentifrice

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54371-471 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE   | 0.22 g in 100 g |

## Inactive Ingredients

| Ingredient Name                                  | Strength |
|--|----------|
| HYDRATED SILICA (UNII: Y6O7T4G8P9)               |          |
| SORBITOL (UNII: 506T60A25R)                      |          |
| WATER (UNII: 059QF0KO0R)                         |          |
| METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)          |          |
| PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)          |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)         |          |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)              |          |

## Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54371-471-01 | 24 g in 1 TUBE      |                      |                    |
| 2 | NDC:54371-471-02 | 43 g in 1 TUBE      |                      |                    |
| 3 | NDC:54371-471-03 | 78 g in 1 TUBE      |                      |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356                                  | 10/31/2011           |                    |

**Labeler** - Oraline, Inc. (179259361)

**Registrant** - Oraline, Inc. (179259361)

## Establishment

| Name   | Address | ID/FEI    | Business Operations    |
|--|---------|-----------|------------------------|
| Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd. |         | 527127383 | manufacture(54371-471) |

Revised: 11/2012

Oraline, Inc.