# COLGATE ANTICAVITY KIT-sodium monofluorophosphate paste, dentifrice Yangzhou Huayin Tourist Daily Necessities Co.,LTD

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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# **Anticavity Toothpaste Kit**

## **Active ingredient**

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

### **Purpose**

Anticavity

#### Use

helps protect against cavities

# Warnings

**Keep out of the 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 right away.

#### **Directions**

| adults and children 2  | brush teeth thoroughly, preferably after each meal or<br>at least twice a day, or as directed by a dentist or<br>physician |
|------------------------|--|
| CHIMPON A TO B VOORS   | use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)                            |
| children under 2 years | ask a dentist or physician   |

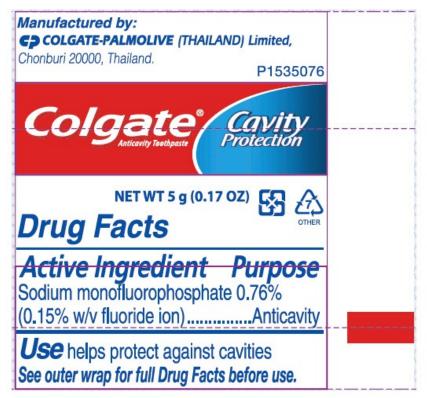
# **Inactive ingredients**

dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin

#### Questions or comments?

Call toll-free **1-800-468-6502** 

PRINCIPAL DISPLAY PANEL - 5g Tube Label



| Drug Facts   | Drug Facts (continued)   |  |  |  |
|--|--|--|--|--|
| Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)Anticavity                              | <b>Directions</b> 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 physician |  |  |
|  | children 2 to 6 years  | use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)                      |  |  |
| Use helps protect against cavities   | children under 2 years   | ask a dentist or physician   |  |  |
| Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, | Inactive ingredients dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin |  |  |  |
| get medical help or contact a Poison Control Center right away.  | ( Questions  | or comments? Call to l-free 1-800-468-6502   |  |  |

Read this full drug facts information before use

ZP3100161

#### COLGATE ANTICAVITY KIT

sodium monofluorophosphate paste, dentifrice

| <b>Product Information</b> |                |                    |               |
|----------------------------|----------------|--------------------|---------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:73181-166 |
| Route of Administration    | DENTAL         |                    |               |

|      | Active Ingredient/Active Moiety   |                      |                  |  |  |
|------|---|----------------------|------------------|--|--|
|      | Ingredient Name   | Basis of<br>Strength | Strength         |  |  |
| - 11 | <b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION         | 7.6 mg<br>in 1 g |  |  |

### **Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) |          |
| WATER (UNII: 059QF0KO0R)                                  |          |
| SORBITOL (UNII: 506T60A25R)                               |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                  |          |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)        |          |
| SODIUM PYROPHO SPHATE (UNII: O352864B8Z)                  |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                       |          |
| LIMO NENE, (+/-)- (UNII: 9 MC3I34447)                     |          |

| I | Packaging        |  |                      |                    |
|---|------------------|--|----------------------|--------------------|
| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
| 1 | NDC:73181-166-88 | 1 in 1 PACKAGE                                   | 06/14/2019           |                    |
| 1 |                  | 5 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part355                                  | 06/14/2019           |                    |  |
|                       |  |                      |                    |  |

# Labeler - Yangzhou Huayin Tourist Daily Necessities Co.,LTD (679949982)

# **Registrant** - Yangzhou Huayin Tourist Daily Necessities Co.,LTD (679949982)

| Establishment                                 |         |           |                        |  |
|---|---------|-----------|------------------------|--|
| Name  | Address | ID/FEI    | Business Operations    |  |
| Colgate-Palmolive (Thailand) Limited - Branch |         | 672044552 | manufacture(73181-166) |  |

| Establishment                                     |         |           |                            |  |
|---|---------|-----------|----------------------------|--|
| Name  | Address | ID/FEI    | <b>Business Operations</b> |  |
| Yangzhou Huayin Tourist Daily Necessities Co.,LTD |         | 679949982 | manufacture(73181-166)     |  |

Revised: 12/2020 Yangzhou Huayin Tourist Daily Necessities Co.,LTD