

**MAXIMUM SECURITY- sodium fluoride gel, dentifrice**  
**Daxal Cosmetics Private Limited**

*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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**Maximum Security Gel Toothpaste**

**ACTIVE INGREDIENT**

Sodium Fluoride - 0.22% (0.1% w/v fluoride ion)

**DRUG FACTS**

**PURPOSE**

Anticavity Toothpaste.

**USE**

Helps protect against cavities.

**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.

**DIRECTIONS:**

Adults & Children 6 years of age & older : Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

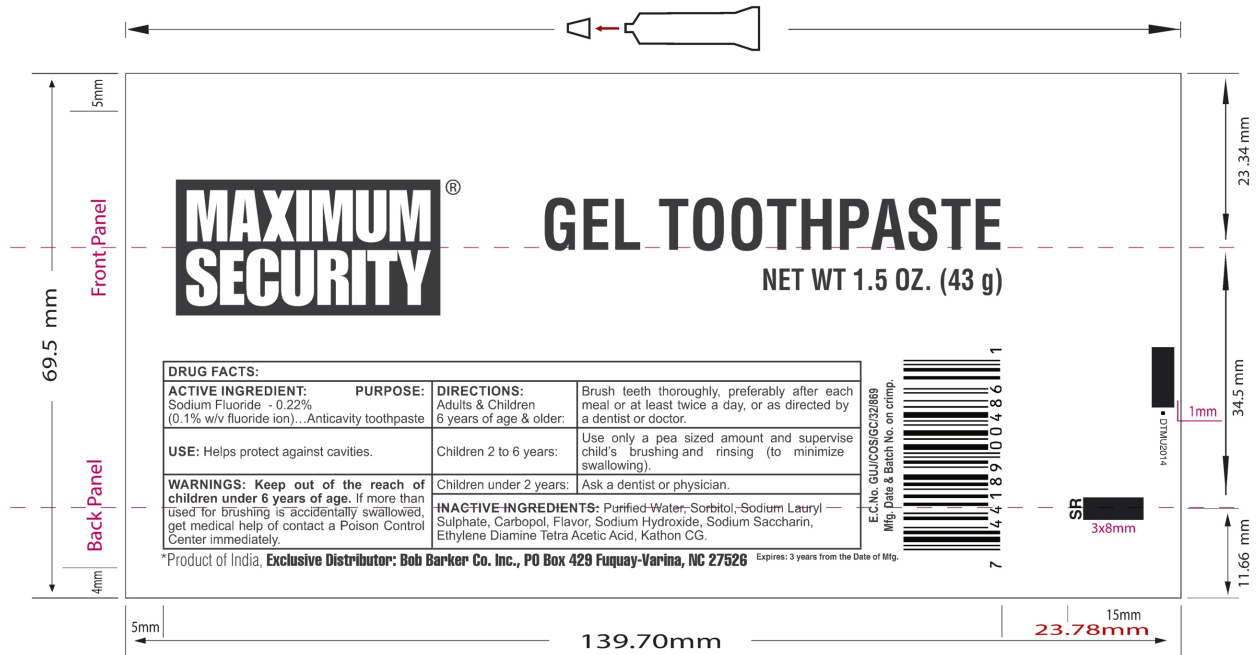
Children 2 to 6 years : Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).

Children under 2 years : Ask a dentist or physician.

**INACTIVE INGREDIENTS:**

Purified Water, Sorbitol, Sodium Lauryl Sulphate, Carbopol, Flavor, Sodium Hydroxide, Sodium Saccharin, Ethylene Diamine Tetra Acetic Acid, Kathon CG.

**PRINCIPAL DISPLAY PANEL - 43 g Tube**



## MAXIMUM SECURITY

sodium fluoride gel, dentifrice

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76001-002 |
| <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      | 0.22 g in 100 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)  |          |
| <b>WATER</b> (UNII: 059QF0K00R)   |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)  |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)   |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                                     |          |
| <b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)                    |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)  |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)  |          |
| <b>METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE</b> (UNII: 15O9QS218W) |          |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76001-002-01 | 4.25 g in 1 PACKET; Type 0: Not a Combination Product | 01/01/2018           |                    |
| 2 | NDC:76001-002-02 | 17 g in 1 TUBE; Type 0: Not a Combination Product     | 01/01/2018           |                    |
| 3 | NDC:76001-002-03 | 24 g in 1 TUBE; Type 0: Not a Combination Product     | 01/01/2018           |                    |
| 4 | NDC:76001-002-04 | 43 g in 1 TUBE; Type 0: Not a Combination Product     | 01/01/2018           |                    |
| 5 | NDC:76001-002-05 | 78 g in 1 TUBE; Type 0: Not a Combination Product     | 01/01/2018           |                    |
| 6 | NDC:76001-002-06 | 130 g in 1 TUBE; Type 0: Not a Combination Product    | 01/01/2018           |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355                                  | 01/01/2018           |                    |

**Labeler** - Daxal Cosmetics Private Limited (650497790)

## Establishment

| Name                            | Address | ID/FEI    | Business Operations    |
|---------------------------------|---------|-----------|------------------------|
| Daxal Cosmetics Private Limited |         | 650497790 | manufacture(76001-002) |

Revised: 8/2019

Daxal Cosmetics Private Limited