

**MAXIMUM SECURITY ANTICAVITY- sodium fluoride gel**

**Bob Barker Company, 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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**MAXIMUM SECURITY ANTICAVITY TOOTHPASTE**

***Drug Facts***

***Active ingredient:***

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

***Purpose:***

Anticavity toothpaste

***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 immediately.

***Directions:***

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|   |  |
|---|--|
| 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. |
|-------------------------|-----------------------------|

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***Inactive ingredients:***

Water, Sorbitol, Sodium Lauryl Sulfate, Carbomer, Sodium Saccharin, Sodium Hydroxide, PEG-40 Hydrogenated Castor Oil, Flavor, Sodium Benzoate

**Package Labeling:**

# MAXIMUM SECURITY<sup>®</sup>

## ANTICAVITY GEL TOOTHPASTE

Sodium Fluoride 0.22%

Fresh Mint Flavor  
NET WT .15 OZ (4.25g)

| <b>Drug Facts</b>  |  | <b>Drug Facts (continued)</b>  |  |
|--|--|--|--|
| <b>Active ingredient:</b><br>Sodium Fluoride - 0.22%<br>(0.1% w/v fluoride ion)...   | <b>Purpose:</b><br>Anticavity toothpaste | <b>Directions:</b><br>Adults & Children<br>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. |
| <b>Use:</b> Helps protect against cavities.  |  | Children 2 to 6 years:   | Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).                   |
| <b>Warnings:</b><br>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 immediately. |  | Children under 2 years:  | Ask a dentist or physician.  |
|  |  | <b>Inactive ingredients:</b> Water, Sorbitol, Sodium Lauryl Sulfate, Carbomer, Sodium Saccharin, Sodium Hydroxide, PEG-40 Hydrogenated Castor Oil, Flavor, Sodium Benzoate |  |

E.C.No. GUJ/COS/GC/32/889  
Mfg. Date & Batch No. on crimp.

Made in India Dist. by Bob Barker Co. Inc. Fuquay-Varina, NC 27526

Package Labeling:

**MAXIMUM SECURITY**®

# ANTICAVITY GEL TOOTHPASTE

Sodium Fluoride 0.22%

**Fresh Mint Flavor**

NET WT 4.6 OZ. (130 g)

| Drug Facts  |                                       | Drug Facts (continued)                                       |   |
|---|---------------------------------------|--|---|
| <b>Active ingredient:</b> Sodium Fluoride - 0.22% (0.1% w/v fluoride ion)...  | <b>Purpose:</b> Anticavity toothpaste | <b>Directions:</b> 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.                            |
| <b>Use:</b> Helps protect against cavities.   |                                       | Children 2 to 6 years:                                       | Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).  |
| <b>Warnings:</b> 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 immediately. |                                       | Children under 2 years:                                      | Ask a dentist or physician.   |
|   |                                       | <b>Inactive ingredients:</b>                                 | Water, Sorbitol, Sodium Lauryl Sulfate, Carbomer, Sodium Saccharin, Sodium Hydroxide, PEG-40 Hydrogenated Castor Oil, Flavor, Sodium Benzoate |

E.C.No. GUJ/COS/GC/32869  
Mfg. Date & Batch No. on crimp.

Made in India Dist. by Bob Barker Co. Inc. Fuquay-Varina, NC 27526

## MAXIMUM SECURITY ANTICAVITY

sodium fluoride gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53247-200 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 2.2 mg in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| WATER (UNII: 059QF0K00R)                                   |          |
| SORBITOL (UNII: 506T60A25R)                                |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                   |          |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                        |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)                        |          |
| POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)     |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                         |          |
| METHYL SALICYLATE (UNII: LAV5U5022Y)                       |          |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53247-200-42 | 4.25 g in 1 PACKET; Type 0: Not a Combination Product | 01/29/2020           |                    |
| 2 | NDC:53247-200-13 | 130 g in 1 TUBE; Type 0: Not a Combination Product    | 01/29/2020           |                    |

  

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part355                                  | 01/29/2020           |                    |

**Labeler** - Bob Barker Company, Inc. (058525536)

Revised: 1/2020

Bob Barker Company, Inc.