MAXIXUM SECURITY GEL TOOTHPASTE- fluoride toothpaste paste, dentifrice **Dabur India 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.

MAXIMUM SECURITY® GEL TOOTHPASTE

NET WT 4.6 OZ

DRUG FACTS:

ACTIVE INGREDIENT

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

PURPOSE

Anticavity.

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 physician.

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, Carbopol, Sodium Lauryl Sulphate, Flavor, Poly Ethylene Glycol 1500, Sodium Saccharin, Precipitated Silica, Sodium Carboxy Methyl Cellulose, Methyl Paraben, Propyl Paraben.

Product of India,

Exclusive Distributor: Bob Barker Co. Inc.,

Phone: 1-800-334-9880.

Expires: 3 years from the Date of Mfg.

C.No. DNH/COS/DNH/52

Mfg. Date & Batch No. on crimp.

24.06.2009

MAXIMUM SECURITY GEL TOOTHPASTE ACTIVE INGREDIENT: SODIUM FLUORIDE - 0.22 % (0.1% w/v fluoride Ion) SR. NO. INGREDIENTS

- 1. Treated water
- 2. Sorbitol
- 3. Carbopol
- 4. Sodium lauryl sulphate
- 5. Flavor
- 6. Polyethylene glycol 1500
- 7. Sodium saccharin
- 8. Precipitated Silica
- 9. Sodium Carboxy Methyl Cellulose
- 10. Methyl Paraben
- 11. Propyl Paraben

Tube Label

MAXIMUM SECURITY® GEL TOOTHPASTE

NET WT 4.6 0Z.(130g)



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MAXIXUM SECURITY GEL TOOTHPASTE

fluoride toothpaste paste, dentifrice

Prod	uct Inf	formation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:68747-6030

Route of Administration DENTAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	SODIUM FLUORIDE	2.2 mg in 1 g

Inactive Ingredients

Ingredient Name

Strength

WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)				
METHYLPARABEN (UNII: A2I8 C7HI9 T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT (MINT)	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68747-6030-1	130 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	08/25/2009		

Labeler - Dabur India Limited (650319218)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dabur India Limited		650319218	MANUFACTURE	

Revised: 8/2008 Dabur India Limited