

**BURST WONDERFULLY WHITENING ANTI CAVITY- sodium fluoride paste, dentifrice  
BURST.USA.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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**Burst Toothpaste**

***Active Ingredient***

Sodium fluoride 0.243%

***Purpose***

Anticavity

***Uses***

Aids in the prevention of dental cavities

***Keep out of the reach of children  
under 6 years of age.***

***Warnings***

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 yrs and older brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. children under 6 yrs to minimize swallowing use a pea-sized amount and brushing until good habits are established. children under 2 years: ask a dentist or physician

***Inactive ingredients***

benzyl alcohol, cellulose gum, flavor, glycerin, PEG-32, propylene glycol, PVM/MA copolymer, silica, sodium benzoate, sodium hydroxide, sodium lauryl sulfate, sodium saccharin, sorbitol, titanium dioxide, water, xanthan gum

**Package Label**

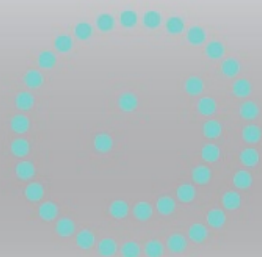
We know you know this BURST.

<b>Drug Facts (continued)</b>		<b>Drug Facts</b>
<b>Directions</b> brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician. children under 6 yrs to minimize swallowing use a pea-sized amount and supervise brushing until good habits are established.	<b>Purpose</b> Anticavity	
<b>Warnings</b> 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 right away.	<b>Active ingredient</b> Sodium fluoride 0.243%	<b>Uses</b> Aids in the prevention of dental cavities.
<b>Inactive ingredients</b> benzyl alcohol, cellulose gum, flavor, glycerin, PEG-32, propylene glycol, PVM/MA copolymer, silica, sodium benzoate, sodium hydroxide, sodium lauryl sulfate, sodium saccharin, sorbitol, titanium dioxide, triclosan, water, xanthan gum	<b>Directions</b> adults and children 2 yrs. and older	<b>Warnings</b> 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 right away.

**BURST USA INC**  
1447 Second Street,  
Santa Monica, CA 90401  
Made in INDIA  
bursttoothpaste.com



11227/01/1 (\*\*)



**BURST**

Mint Anticavity Fluoride toothpaste

NET WT 4.7 oz (133 g)

**WONDERFULLY  
WHITENING**

## BURST WONDERFULLY WHITENING ANTI CAVITY

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71275-001
<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	0.243 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRICLOSAN (UNII: 4NM5039Y5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71275-001-47	133 g in 1 TUBE; Type 0: Not a Combination Product	02/20/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/20/2017	

**Labeler** - BURST.USA.Inc (080474113)