

CHARM TEX- sodium fluoride paste, dentifrice
Charm Tex, 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.

Charm-Tex
FLUORIDE GEL TOOTHPASTE

DRUG FACTS

Active ingredient

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

Purpose

Anticavity

Use

helps protect against cavities.

Warning

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 centre immediately.

Inactive ingredient

Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SMC, Sodium Lauryl Sulfate.

Directions

Adults and children 6 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 a 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.

Exclusive Distributor: **Charm-Tex, Inc.** USA

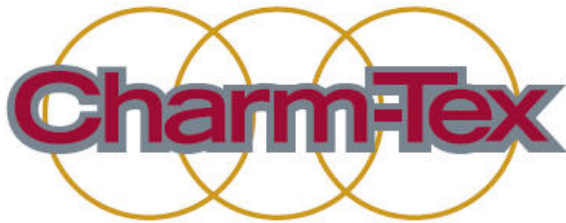
PRINCIPAL DISPLAY PANEL - 42.5 Grams Tube Label

Charm-Tex

FLUORIDE GEL TOOTHPASTE

Net Wt. 1.5 oz.

42.5 Grams



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FLUORIDE GEL TOOTHPASTE

DRUG FACTS		DIRECTIONS
Active ingredient: Sodium Fluoride 0.22% (0.1% w/v fluoride ion)	Purpose Anticavity	Adults and children 6 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 a physician.
Use: 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.
Warning: 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 centre immediately.		Children under 2 years: Ask a dentist or physician.
Inactive ingredient: Sorbitol, Silica, Methyl Paraben Sodium, Propyl Paraben Sodium, Flavour, Sodium Saccharin, Treated water, SCMC, Sodium Lauryl Sulfate.		
Product of India, Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM		
N.C. No.: DD/COS/DD/C340		Expiry: 2 years from the date of Mfg.
Mfg. Date & Batch No. on crimp		

CHARM TEX

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40057-1001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	0.22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	62 g in 100 g
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)	

Methylparaben Sodium (UNII: CR6K9C2NHK)

Propylparaben Sodium (UNII: 625NNB0G9N)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40057-1001-1	141 g in 1 TUBE		
2	NDC:40057-1001-2	85 g in 1 TUBE		
3	NDC:40057-1001-3	42.5 g in 1 TUBE		
4	NDC:40057-1001-4	24 g in 1 TUBE		
5	NDC:40057-1001-5	17 g in 1 TUBE		
6	NDC:40057-1001-6	4.24 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	06/01/2011	

Labeler - Charm Tex, Inc. (058347543)

Revised: 12/2011

Charm Tex, Inc.