

ZOHAR TOOTHPASTE COOL MINT- sodium monofluorophosphate paste, dentifrice
Broom Lane Enterprises

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.

Drug Facts

Active Ingredients

Sodium monofluorophosphate 1.15% (1500 ppm/ 0.15% w/v fluoride ion)

Purpose

Anticavity

Uses

Aids in the prevention of dental 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 right away.

Directions

- do not swallow
- supervise children as necessary until capable of using without supervision.

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 physician.
children 6 to 12 years	instruct in good brushing and rinsing habits(to minimise swallowing)
children under 6 years	do not use unless directed by dentist or doctor

Calcium Carbonate, Water, Glycerine, Hydrated Silica, Sodium Lauryl Sulphate, Silica, Cellulose gum, Flavour, Carvone, Sodium Saccharin, Methylparaben, Limonene

Questions?

call 718 256 9100

you may also report serious side effects to this phone number

Principal Display Panel

Zohar
FLUORIDE
TOOTHPASTE

COOL MINT

HELPS FIGHT TOOTH DECAY

Net Wt. 4oz/75ml



ZOHAR TOOTHPASTE COOL MINT

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55754-122
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	11.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

CARVONE, (+/-)- (UNII: 75GK9XIA8I)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

METHYLPARABEN (UNII: A2I8C7HI9T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55754-122-01	1 in 1 CARTON		
1		113.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/28/2011	

Labeler - Broom Lane Enterprises (211243172)

Establishment

Name	Address	ID/FEI	Business Operations
Suzhou City Jinmao Daily Chemicals Co., Ltd		547664185	manufacture

Revised: 2/2011

Broom Lane Enterprises