

ZOHAR TOOTHPASTE REGULAR 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

REGULAR MINT

HELPS FIGHT TOOTH DECAY

Net Wt. 4oz/75ml



ZOHAR TOOTHPASTE REGULAR MINT

sodium monofluorophosphate paste, dentifrice

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55754-123 |
| 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:55754-123-01 | 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