

ANCALIMA-GOOD MORNING- sodium monofluorophosphate paste, dentifrice Ancalima

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.

Ancalima- Good morning

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

Purpose

Anticavity Toothpaste

Use

aids in the prevention of dental cavities

Warnings

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 Center immediately

Directions

- Do not Swallow
- Supervise children as necessary until capable of using without supervision
- Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing)
- **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 under 6 years of age:** Do not use unless directed by a dentist or physician

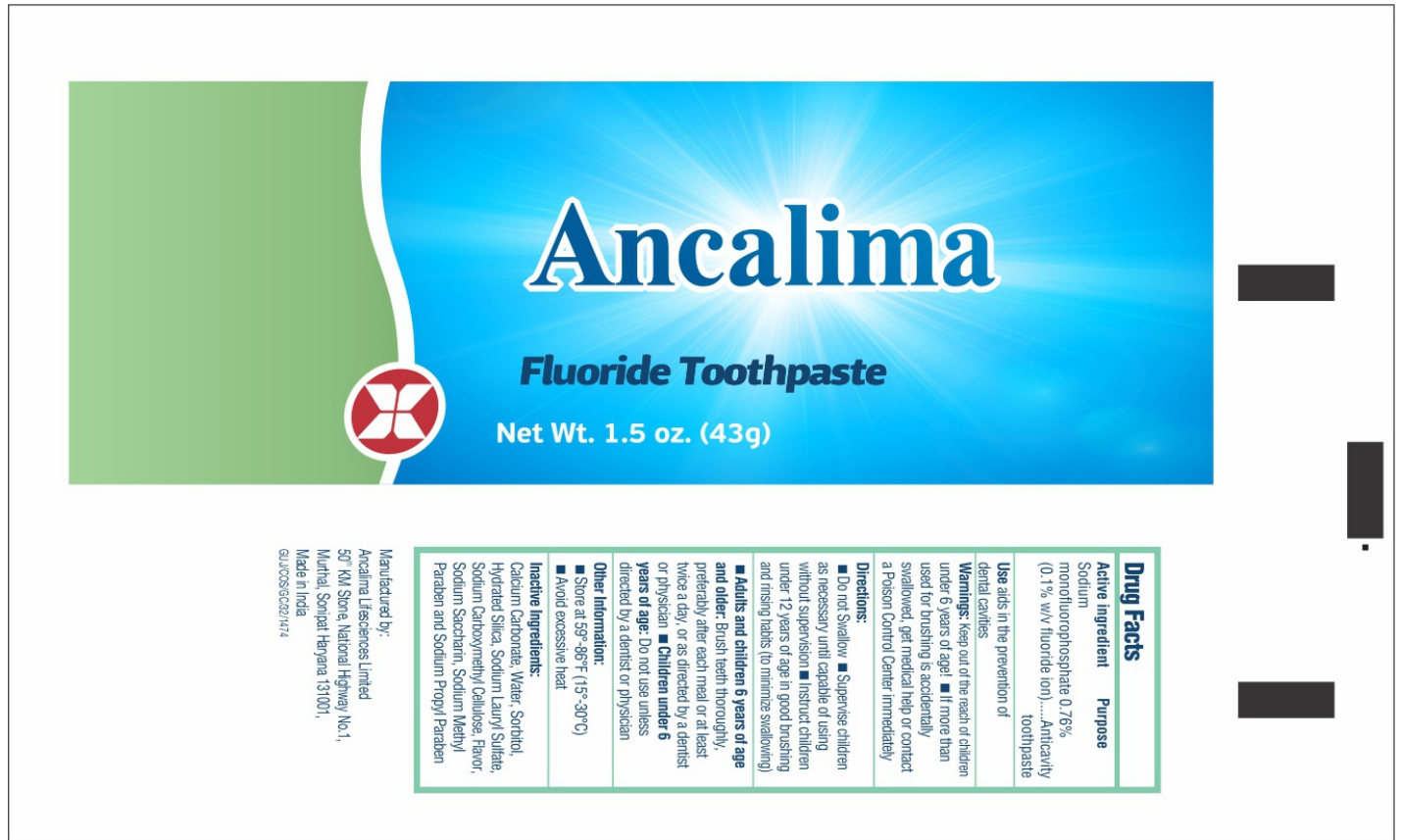
Other Information

- Store at 59°-86°F (15°-30°C)
- Avoid excessive heat

Inactive Ingredients

Calcium Carbonate, Water, Sorbitol, Hydrated Silica, Sodium Lauryl Sulfate, Sodium Carboxymethyl Cellulose, Flavor, Sodium Saccharin, Sodium Methyl Paraben, Sodium Propyl Paraben

PRINCIPAL DISPLAY PANEL - 43 g Tube Carton



ANCALIMA-GOOD MORNING		
sodium monofluorophosphate paste, dentifrice		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:73014-1073
Route of Administration	DENTAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g
Inactive Ingredients		
Ingredient Name	Strength	

CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73014-1073-6	43 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/15/2015	

Labeler - Ancalima (676760093)

Establishment

Name	Address	ID/FEI	Business Operations
ANCALIMA LIFESCIENCES LIMITED		676760093	manufacture(73014-1073)

Revised: 5/2021

Ancalima