

THE HUMBLECO NATURAL FRESH MINT- sodium fluoride paste, dentifrice
The Humble Company 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.

The HumbleCo. Natural Toothpaste Fresh Mint

Drug Facts

Active ingredient

Sodium fluoride 0.237%

Purpose

anticavity

Use/Indication

aids in the prevention of dental cavities

Warnings

When using this product

if irritation occurs discontinue use.

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

> adults and children 2 years of age and older:

- apply toothpaste onto a toothbrush

- brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

> children under 2 years of age: Consult a dentist or doctor

Other information

store below 25 °C (77 °F)

Contact/Questions:

Call 1 (858) 876-5174

Inactive ingredients

HYDROGENATED STARCH HYDROLYSATE, AQUA, HYDRATED SILICA, LAURYL

GLUCOSIDE, XANTHAN GUM, MENTHA PIPERITA OIL, SODIUM FLUORIDE, ZINC GLUCONATE, MENTHOL, STEVIA REBAUDIANA EXTRACT, ALOE BARBADENSIS LEAF JUICE POWDER, SALVIA TRILOBA LEAF EXTRACT, CHAMOMILLA RECUTITA FLOWER EXTRACT, COMMIPHORA MYRRHA RESIN EXTRACT, LIMONENE, CI 77891.

Package Labeling:



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Other information store below 25° C (77°F)	
Contact/Questions: Call 1(800) 555-5555	
NDC Number: To be added here?	
Manufactured in Germany. Distributed by: The Humble Company USA, Inc 4475 Mission Blvd. 92109 San Diego, CA, USA	
Inactive ingredients	
HYDROGENATED STARCH HYDROLYSATE, AQUA, HYDRATED SILICA, LAURYL GLUCOSIDE, XANTHAN GUM, MENTHA PIPERITA OIL, SODIUM FLUORIDE, ZINC GLUCONATE, MENTHOL, STEVIA REBAUDIANA EXTRACT, ALOE BARBADENSIS LEAF JUICE POWDER, SALVIA TRILOBA LEAF EXTRACT, CHAMOMILLA RECUTITA FLOWER EXTRACT, COMMIPHORA MYRRHA RESIN EXTRACT, LIMONENE, CI 77891.	



LABEL USA
Fresh mint 75 ml

THE HUMBLECO NATURAL FRESH MINT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72299-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
MENTHOL (UNII: L7T10EIP3A)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
THREE-LOBE SAGE (UNII: 3V97D33N0K)	
MYRRH (UNII: JC71GJ1F3L)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72299-001-00	75 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2018	

Labeler - The Humble Company USA, Inc (080780354)

Revised: 5/2018

The Humble Company USA, Inc