THERASTOM- antigingivitis/antiplaque mouth rinse rinse Forward Science Technologies LLC

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.

TheraStom

Inactive Ingredients

Calcium Disodium EDTA, Flavor (Peppermint, Eucalyptus, Pink Grapefruit), Glycerin, PEG-40, Propylene Glycol, Water, Xylitol, Zinc Gluconate

Active Ingredient

Cetylpyridinium Chloride 0.075%

Purpose

Antigingivitis/Antiplaque

Use(s)

- Helps control plaque that leads to bleeding gums.
- Helps prevent gingivitis, an early form of gum disease .

Warnings

Stop use and ask a dentist if:

- Gingivitis, bleeding, or redness persists for more than 2 weeks
- You have painful or swollen gums, pus from the gum line, loose teeth, or increased spacing between the teeth.

These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children

Keep out of reach of children under 6 years of age.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Adults and children 12 years or older: Vigorously swish 20 ml (4 teaspoonfuls) of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.

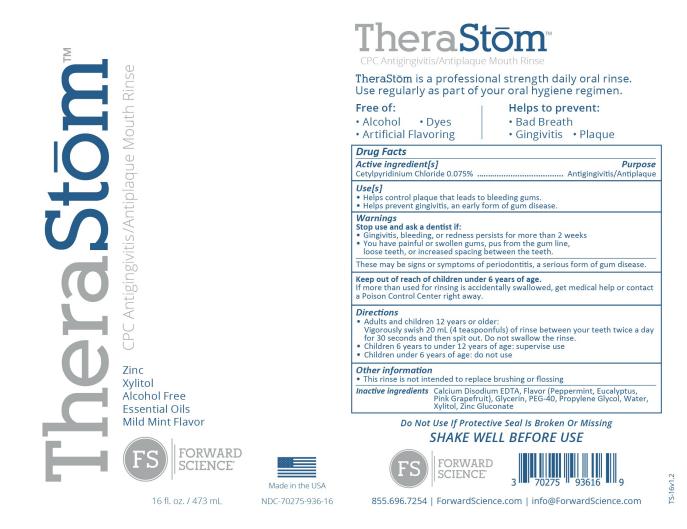
- Children 6 years to under 12 years of age: supervise use
- Children under 6 years of age: do not use

Other information

This rinse is not intended to replace brushing or flossing

Dosage

Vigorously swish 20 ml (4 teaspoonfuls) of rinse between your teeth twice a day for 30 seconds and then spit out.



THERASTOM

 antigingivitis/antiplaque mouth rinse rinse

 Product Information

 Product Type
 HUMAN OTC DRUG

 Route of Administration
 ORAL

 Active Ingredient/Active Moiety

	Ingredient Name	Basis of Streng	th Strength			
CETYLPYRIDINIUM UNII:CUB7JI0JV3)	CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIU	M - CETYLPYRIDINIUM CHLORIDE	0.075 mg in 0.1 mL			
Inactive Ingred	lients					
Ingredient Name						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
EUCALYPTUS OIL (UNII: 2R04ONI662)						
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)						
WATER (UNII: 059QF0KO0R)						
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)						
GLYCERIN (UNII: PDC6A3C0OX)						
GRAPEFRUIT OIL (UNII: YR377U58W9)						
XYLITOL (UNII: VCQ006KQ1E)						
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)						
PEPPERMINT OIL (UNII: AV092KU4JH)						
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	73 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2021				
Marketing Information						
Ma alas tinan		Marketing Start	Marketing End			
Marketing Category	Application Number or Monograph Citation	Date	Date			
		Date 04/05/2021	-			

Labeler - Forward Science Technologies LLC (079212068)

Establishment						
Name	Address	ID/FEI	Business Operations			
Forward Science Technologies LLC		079212068	manufacture(70275-936)			

Revised: 1/2023

Forward Science Technologies LLC