

COOL SENSE CARE PLUS MOUTHWASH- sodium fluoride liquid
Dr.s Medi Co.,Ltd.

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

sodium fluoride

Propolis extract, Turmeric extract, Xylitol, Grapefruit seed extract, Aloe extract, Matricaria extract, Rosemary extract, Green tea extract, Mulberry root extract, L-menthol, Peppermint oil, Polyoxyethylene castor oil, Poloxamer 407, Sodium benzoate, Concentrated glycerin, Steviol glycoside, Flavoring agent, Purified water

Helps prevent and reduce:

Plaque formation

Dental cavities

Gum bleeding, soreness, and inflammation

Halitosis

KEEP OUT OF REACH OF THE CHILDREN

- Adults and children 6 years of age and older:

Rinse for 60 seconds with 10ml (2 teaspoonful) and then spit out

Do not swallow the rinse

Supervise children as necessary until capable of using without supervision

- Children under 6

Consult a dentist or physician

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

Do not swallow

If accidentally swallowed, get medical help or contact Poison Control Center right away.

dental use only

Active Ingredients	Sodium fluoride (0.02%)	
Inactive Ingredients	Propolis extract, Turmeric extract, Xylitol, Grapefruit seed extract, Aloe extract, Matricaria extract, Rosemary extract, Green tea extract, Mulberry root extract, L-menthol, Peppermint oil, Polyoxyethylene castor oil, Poloxamer 407, Sodium benzoate, Concentrated glycerin, Steviol glycoside, Flavoring agent, Purified water	
Purpose	<u>Anticavity</u>	
Uses	Helps prevent and reduce: Plaque formation Dental cavities Gum bleeding, soreness, and inflammation Halitosis	
Warnings	Keep out of reach of children under 6 years of age. Do not swallow If accidentally swallowed, get medical help or contact Poison Control Center right away.	
Directions	Adults and children 6 years of age and older:	Rinse for 60 seconds with 10ml (2 teaspoonful) and then spit out Do not swallow the rinse Supervise children as necessary until capable of using without supervision
	Children under 6:	Consult a dentist or physician
Other information	Store at room temperature(15°C-30°C)	

COOL SENSE CARE PLUS MOUTHWASH

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76670-0002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.02 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76670-0002-1	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/30/2021	

Labeler - Dr.s Medi Co.,Ltd. (694505169)

Registrant - Dr.s Medi Co.,Ltd. (694505169)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.s Medi Co.,Ltd.		694505169	manufacture(76670-0002)

Revised: 7/2021

Dr.s Medi Co.,Ltd.