# SARINA ANTISEPTIC- chlorhexidine digluconate liquid Sarina Accessories, 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.

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#### SARINA ANTISEPTIC MOUTHWASH

#### Active ingredients

Cetylpyridinium Chloride 0.1%.

### Purpose

Antiplaque

#### Use

Helps reduce plaque that leads to

- ginivitis
- bleeding gums

#### **Warnings**

#### Stop use and see your dentist immediately if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gumline, loose teeth, or increasing space between the teeth.

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

#### 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 immediately.

#### Directions

adults and children 12 years vigorously swish 20 milliliters of rinse between teeth twice a day for 30 of age and older seconds then spit out. Do not swallow the rinse

children 6 to 12 years of

age

supervise use

children under 6 years of

do not use

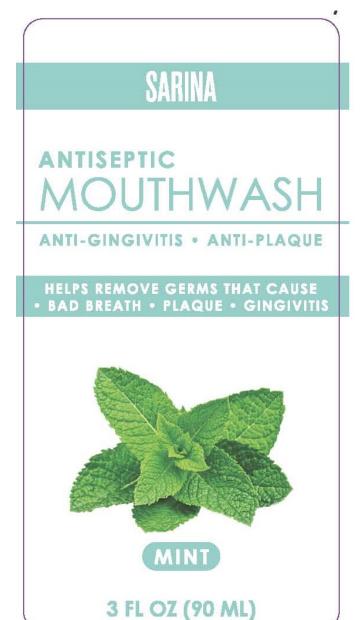
age

#### Other information

- not intended to replace brushing or flossing
- store at room temperature (59°-77°F).
- cold weather may cloud this product, but will not affect its antiseptic properties.

#### **Inactive ingredients**

## Water, Alcohol, PEG-60 Hydrogenated Castor Oil Glycerin Fragrance Sodium Benzoate Mentholum Sodium Saccharin Citric Acid FD&C Blue No.1



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# Distributed by:

Sarina Accessories New York City, NY 10018 Made in China



#### SARINA ANTISEPTIC

chlorhexidine digluconate liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:90106-003

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 O M4SK49 P) (CETYLPYRIDINIUM -	CETYLPYRIDINIUM	1 mg
UNII:CUB7JI0JV3)	CHLORIDE	in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
ALCOHOL (UNII: 3K9958V90M)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)				
MENTHOL (UNII: L7T10EIP3A)				

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:90106-003-	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	08/25/2020			

# **Labeler -** Sarina Accessories, LLC (787043145)

Revised: 8/2020 Sarina Accessories, LLC