

SHOPKO ALCOHOL FREE MULTI ACTION- cetylpyridinium chloride mouthwash
Apollo Health and Beauty Care 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.

Drug Facts

Active ingredient

Cetylpyridinium Chloride 0.07%

Purpose

Antigingivitis/Antiplaque

Uses

- helps reduce plaque that lead to:
- gingivitis
- bleeding gums

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 increasing spacing 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 of age and older: vigorously swish 20 milliliters 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.
- store at room temperature.

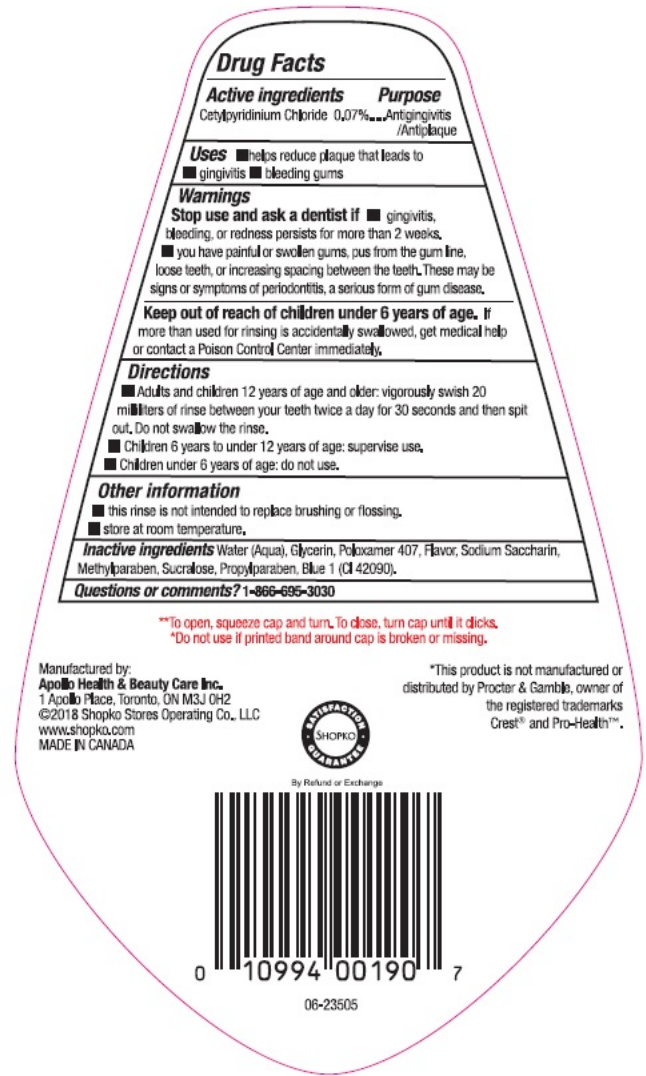
Inactive ingredients

Water (Aqua), Glycerin, Poloxamer 407, Flavor, Sodium Saccharin, Methylparaben, Sucralose, Propylparaben, Blue 1 (CI 42090).

Questions ro comments?

1-866-695-3030

Label Copy



SHOPKO ALCOHOL FREE MULTI ACTION

cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-0 10
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7J10JV3)	CETYL PYRIDINIUM CHLORIDE	0.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7H9T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-010-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/07/2018	

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-010)

Revised: 6/2018

Apollo Health and Beauty Care Inc.