HYVEE PRO CLEAN BLUE MINT- cetylpyridinium chloride liquid HYVEE 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

PURPOSE

ANTIGINGIVITIS/ANTIPLAQUE

USES

HELPS REDUCE AND PREVENT PLAQUE AND GINGIVITIS. HELPS CONTROL PLAQUE BACTERIA THAT CONTRIBUTE TO THE DEVELOPMENT OF GINGIVITIS AND BLEEDING GUMS.

WARNINGS

ASK A DENTIST IF SYMPTOMS PERSIST OR CONDITION WORSENS AFTER REGULAR USE.

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

USE AFTER YOUR NORMAL BRUSHING AND FLOSSING ROUTINE; RINSE TOOTHPASTE FROM MOUTH PRIOR TO USE. ADULTS AND CHILDREN 6 YEARS AND OLDER: RINSE FOR 30 SECONDS WITH 20 ML (4 TEASPOONFULS) TWICE A DAY. DO NOT SWALLOW. CHILDREN 6 YEARS TO UNDER 12 YEARS OF AGE: SUPERVISE USE. CHILDREN UNDER 6 YEARS OF AGE: DO NOT USE.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER (AQUA), GLYCERIN, POLOXAMER 407, FLAVOR, SODIUM SACCHARIN, METHYLPARABEN, SUCRALOSE, PROPYLPARABEN, BLUE 1 (CI 42090).

QUESTIONS OR COMMENTS?

1-800-289-8343

LABEL COPY



Drug Facts Active ingredient Purpose Cetylpyridinium Chloride 0.07 % Antigingivitis/Antiplaque Uses ■ Helps reduce and prevent plaque and gingivitis. ■ Helps control plaque bacteria that contribute to the development of gingivitis and bleeding gums. Warnings Ask a dentist if ■ symptoms persist or condition worsens after regular use 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** Use after your normal brushing and flossing routine; rinse toothpaste from mouth prior to use. Adults and children 6 years and older: Rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day. ■ Do not swallow. ■ Children 6 years to under 12 years of age: supervise use. Children under 6 years of age: do not use. Other Information ■ Store at room temperature. Inactive ingredients: Water (Aqua), Glycerin, Poloxamer 407, Flavor, Sodium Saccharin, Methylparaben, Sucralose, Propylparaben, Blue 1 (CI 42090). Questions or comments? 1-800-289-8343 DO NOT USE IF PRINTED BAND AROUND CAP IS BROKEN OR MISSING TO OPEN: SQUEEZE SMOOTH AREAS ON CAP AND TURN. TO CLOSE: TURN CAP UNTIL IT LOCKS. DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266 MADE IN CANADA SATISFACTION GUARANTEED CALL 1-800-289-8343 www.hy-vee.com *This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Crest[®] and Pro-Health™.

HYVEE PRO CLEAN BLUE MINT

cetylpyridinium chloride liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:42507-553 Route of Administration ORAL

	Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength	
	CETYLPYRIDINIUM CHLO RIDE (UNII: D9 OM4SK49 P) (CETYLPYRIDINIUM -	CETYLPYRIDINIUM	0.7 mg	
1	UNII:CUB7JI0JV3)	CHLORIDE	in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
METHYLPARABEN (UNII: A218 C7HI9 T)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:42507-553-16	474 mL in 1 BOTTLE, PLASTIC			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	09/12/2013			

Labeler - HYVEE INC. (006925671)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(42507-553)	

Revised: 9/2013 HYVEE INC.