# 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.

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#### **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<sup>®</sup> and Pro-Health™.

# HYVEE PRO CLEAN BLUE MINT

cetylpyridinium chloride liquid

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

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (CETYLPYRIDINIUM)	CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER	
GLYCERIN	
POLOXAMER 407	
SACCHARIN SO DIUM	
METHYLPARABEN	
SUCRALOSE	
PROPYLPARABEN	
FD&C BLUE NO. 1	

1	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
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.