

CPH ANTI-BACTERIAL BREATH MIST- cetylpyridinium chloride spray OraLabs

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 0.09%

Purpose

Antibacterial

Keep Out of Reach of Children

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

Uses

Helps fight odor causing bacteria

Warnings

For external use only:

Do not use this product if gums are irritated or bleeding unless directed to do by a doctor or dentist. If more than twice the recommended amount for tongue spraying is accidentally swallowed, get medical help or contact a Poison Control Center immediately. Do not spray into the eyes. Do not spray into the eyes. If spray gets into the eyes, hold eyelids apart and flush the eye continuously with running water for at least 15 minutes.

Directions

Adults and children 12 years of age and older: Spray 3 times in the oral cavity. Children 6-12 years of age: Supervise use. Children under 6 years: Do not use.

Inactive Ingredients

Citric Acid, Flavor, Glycerin, Menthol, PEG-40 Hydrogenated Castor Oil, Potassium Sorbate, Sodium Benzoate, Sucralose, Water.

Package/Label Principal Display Panel



CPH ANTI-BACTERIAL BREATH MIST

cetylpyridinium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-179
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	CETYLPIRIDINIUM CHLORIDE	1.11 g in 13.0 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	11.18 mL in 13.0 mL
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	1.3 mL in 13.0 mL
MENTHOL, (+)- (UNII: C6B10E8P3W)	.0065 mL in 13.0 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	.039 mL in 13.0 mL

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-179-06	13.0 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/15/2022	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-179) , LABEL(63645-179)

Revised: 4/2022

OraLabs