

BREATHRX WITH ZYTEX- cetylpyridinium chloride rinse
Discus Dental, 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.

BreathRx Anti-bacterial Mouth Rinse

Warnings: Keep out of reach of children under 6 years of age.

Other Information

- Store at controlled room temperature 15 ° - 30 °C (59 ° - 86 °F)

Inactive Ingredients

Blue 1, Citric acid, Cocamidopropyl Betaine, Flavor (Mint, Thymol and Eucalyptus Oil), PEG-40 Hydrogenated Castor oil, Poloxamer 407, Propylene Glycol, Sodium Saccharin, Sorbitol, Water, Xylitol, Zinc gluconate.

Use:

- helps prevent plaque that leads to gingivitis
- helps fight odor-causing bacteria

Antibacterial, antiplaque, antigingivitis

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

- **Do not use if seal is broken**

Directions:

- Do not swallow rinse.
- Adults and children 12 years of age and older: vigorously swish 1/2 oz. (20 mL) of rinse, twice a day, for 30 seconds then spit out.
- Children 6 years to under 12 years: supervise use.
- Children under 6 years of age: do not use

Active Ingredients

Cetylpyridinium chloride 0.075%

Packaging Labels (Bottle Front and Back Labels)

Front Label

PHILIPS
sonicare

Breath**Rx**

Antibacterial mouth rinse

Clinically proven to reduce
bad breath 3x better¹

Zinc and
essential oils



Neutralizes
bad breath

Alcohol free | Sugar free | Clean mint

8 fl. oz. 237 mL

4235 020 82952 141008

Back Label



The BreathRx system fights the negative bacteria that cause bad breath with a combination of zinc, essential oils, CPC, and mechanical action.

¹Reduces bad breath 3x better than the leading mouth rinse after only 2 weeks of daily use.

Drug Facts

Active Ingredient: Cetylpyridinium chloride 0.075%

Purpose: Antibacterial, antiplaque, antigingivitis

Use: Helps prevent plaque that leads to gingivitis. Helps fight odor-causing bacteria.

Warnings: 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 right away.

Do not use if seal is broken.

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.

Directions: Do not swallow rinse. Adults and children 12 years of age and older: vigorously swish 1/2 oz. (20 mL) of rinse, twice a day, for 30 seconds and then spit out. Children 6 years to under 12 years: supervise use. Children under 6 years of age: do not use.

Other Information: Store at controlled room temperature 15° - 30°C (59° - 86°F)

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Questions or comments? Call: 1-800-422-9448

Manufactured by: Discus Dental, LLC
Ontario, CA 91761 USA philipsoralhealthcare.com

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BREATHRX WITH ZYTEX

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64854-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
THYMOL (UNII: 3J50XA376E)	
MINT (UNII: FV98Z8G1TP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue (Light blue)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64854-014-07	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/21/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/21/2006	

Labeler - Discus Dental, LLC (831726109)

Registrant - Discus Dental, LLC (831726109)

Establishment

Name	Address	ID/FEI	Business Operations
Discus Dental, LLC		831726109	manufacture(64854-014)

Revised: 12/2022

Discus Dental, LLC