

**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.*

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**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%

**Package Labels (Bottle Front and Back Labels)**

Front Label

**PHILIPS**  
**sonicare**

Breath**Rx**

**Antibacterial mouth rinse**

Clinically proven to reduce  
bad breath 3x better<sup>1</sup>

Zinc and  
essential oils



Neutralizes  
bad breath

Alcohol free | Sugar free  
Clean mint

2 fl.oz. 59 mL

4235 020 72372 141008

Back Label

# 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.

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

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

Manufactured by: Discus Dental, LLC  
Ontario, CA 91761 USA  
[philipsoralhealthcare.com](http://philipsoralhealthcare.com)



4235 020 72382

## BREATHRX WITH ZYTEX

cetylpyridinium chloride rinse

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	CETYLPIRIDINIUM CHLORIDE	.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: FV98Z8GITP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### Product Characteristics

<b>Color</b>	blue (Light blue)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64854-014-06	59 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: 9/2019

Discus Dental, LLC