

BREATHRX WITH ZYTEX- cetylpyridinium chloride, sodium fluoride
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.

Starter Kit

Toothpaste

Active ingredients

Sodium Fluoride 0.243%

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

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

Warnings

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

Directions

Do not swallow rinse. Supervise children as necessary until capable of using without supervision.

Adults and children 2 years of age and older	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
Children 2 years to 6 years	Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
Children under 2 years of age	Consult a dentist or doctor.

Other information

- store at 15° - 30°C (59° - 86°F)
- twist off cap and remove foil seal

Inactive ingredients

Blue 1, Cellulose Gum, Flavor (Mint, Thymol and Eucalyptus Oil), Glycerin, Mica & Titanium Dioxide, PEG-12, Silica, Sodium Lauryl Sulfate, Sodium Methyl Cocoyl Taurate, Sodium Saccharin, Sorbitol, Tetrapotassium Pyrophosphate, Tetrasodium Pyrophosphate, Water, Xanthan Gum, Xylitol, Zinc gluconate

Tongue Spray

Active Ingredient

Cetylpyridinium chloride 0.085%

Purpose

Antibacterial

Use

Helps fight odor-causing bacteria

Warnings

Do not use if seal is broken.

Warnings

Keep out of reach of children under 6 years of age. 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. If spray gets into eyes, hold eyelids apart and flush the eye continuously with running water for at least 15 minutes.

Directions

Shake before use

adults and	spray 2-3 times on
children 12	the back of the
years of age	tongue and gently
and older	scape with cleaner
children 6 -	
12 years of	supervise use
age	

children	
under 6	do not use
years	

Other Information

Store at 15°–30°C (59°–86°F)

Inactive Ingredients

Blue 1, Flavor (Peppermint Oil, Thymol and Eucalyptus Oil), PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, Propylene Glycol, Sodium Saccharin, Water, Zinc Gluconate

Mouth Rinse

Active Ingredients

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.

Warnings

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

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 teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Directions

Do not swallow rinse.

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

years _____

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

Other Information

- store at 15° - 30°C (59° - 86°F)
- this rinse is not intended to replace brushing or flossing

Do not use products if seals are broken or missing.

Package Label

PHILIPS sonicare



BreathRx

Starter Kit

- 4 oz. whitening toothpaste
- 8 fl. oz. antibacterial mouth rinse
- 2 fl. oz. antibacterial tongue spray
- 2 tongue cleaners



Clinically proven to reduce
bad breath 3x better¹



¹Reduces bad breath 3x better than the leading mouth rinse after only 2 weeks of daily use.
²Among dentists who recommend a breath care system. The BreathRx breath care system includes toothpaste, tongue scraper, tongue spray, and mouth rinse.



BreathRx

Long lasting fresh breath in three easy steps:



The Science of Fresh Breath

The BreathRx system is scientifically formulated to fight the causes of bad breath. A powerful combination of anti-bacterial CPC and Zytex, a unique blend of zinc and essential oils, attacks bad breath at the source, destroying harmful bacteria and neutralizing odors for long lasting freshness.

Whitening toothpaste

Antibacterial tongue spray

Antibacterial mouth rinse

Drug Facts

Active ingredient	Purpose
Sodium Fluoride 0.243%	Anticavity

Use

aids in the prevention of dental cavities

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact Poison Control Center right away.

Directions

Do not swallow Supervise children as necessary until capable of using without supervision.

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
children 2 to 6 years	instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
children under 2 years of age	consult a dentist or doctor.

Other information

- store at 15° - 30°C (59° - 86°F)
- twist off cap and remove foil seal

Inactive ingredients Blue 1, Cellulose Gum, Flavor (Mint, Thymol and Eucalyptus Oil), Glycerin, Mica & Titanium Dioxide, PEG-12, Silica, Sodium Lauryl Sulfate, Sodium Methyl Cocoyl Taurate, Sodium Saccharin, Sorbitol, Tetrapotassium Pyrophosphate, Tetrasodium Pyrophosphate, Water, Xanthan Gum, Xylitol, Zinc Gluconate

Drug Facts

Active ingredient	Purpose
Cetylpyridinium chloride 0.085%	Antibacterial

Use

helps fight odor-causing bacteria.

Warnings

Keep out of reach of children under 6 years of age. 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. If spray gets into eyes, hold eyelids apart and flush the eye continuously with running water for at least 15 minutes.

Directions

Shake before use

adults and children 12 years of age and older	spray 2-3 times on the back of the tongue and gently scrape with cleaner
children 6-12 years of age	supervise use
children under 6 years	do not use

Other information

store at 15° - 30°C (59° - 86°F)

Inactive ingredients Blue 1, Flavor (Peppermint Oil, Thymol and Eucalyptus Oil), Peg 8 Dimethicone, Peg-40 Hydrogenated Castor Oil, Propylene Glycol, Sodium Saccharin, Water, Zinc Gluconate

Do not use products if seals are broken or missing.

Drug Facts

Active ingredient	Purpose
Cetylpyridinium chloride 0.075%	Antibacterial, antiplaque, antigingivitis

Uses

- 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.

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 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	do not use

Other information

- store at 15° - 30°C (59° - 86°F)
- this rinse is not intended to replace brushing or flossing

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

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Questions or Comments? Call 1-800-422-9448

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BREATHRX WITH ZYTEX

cetylpyridinium chloride, sodium fluoride kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64854-044

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64854-044-01	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	09/18/2014	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	237 mL
Part 2	1 BOTTLE, PLASTIC	59 mL
Part 3	1 TUBE	112 g

Part 1 of 3

BREATHRX WITH ZYTEX

cetylpyridinium chloride rinse

Product Information

Item Code (Source)	NDC:64854-014
Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
MINT (UNII: FV98Z8G1TP)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
WATER (UNII: 059QF0KO0R)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
THYMOL (UNII: 3J50XA376E)	

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:64854-014-11	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

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

Part 2 of 3

BREATHRX WITH ZYTEX

cetylpyridinium chloride spray

Product Information

Item Code (Source)	NDC:64854-012
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7JJOJV3)	CETYLPIRIDINIUM CHLORIDE	0.85 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PEPPERMINT OIL (UNII: AV092KU4JH)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
WATER (UNII: 059QF0KO0R)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
THYMOL (UNII: 3J50XA376E)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

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:64854-012-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

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

Part 3 of 3

BREATHRX WITH ZYTEX

sodium fluoride paste, dentifrice

Product Information

Item Code (Source)	NDC:64854-018
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

XYLITOL (UNII: VCQ006KQ1E)
SORBITOL (UNII: 506T60A25R)
MINT (UNII: FV98Z8GITP)
CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)
WATER (UNII: 059QF0KO0R)
MICA (UNII: V8A1AW0880)
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
GLYCERIN (UNII: PDC6A3C0OX)
THYMOL (UNII: 3J50XA376E)
EUCALYPTUS OIL (UNII: 2R04ONI662)
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
XANTHAN GUM (UNII: TTV12P4NEE)
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)

Product Characteristics

Color	blue (Blue with sparkles)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64854-018-01	112 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/21/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356,part355	09/18/2014	

Labeler - Discus Dental, LLC (831726109)

Registrant - Discus Dental, LLC (831726109)

Establishment

Name	Address	ID/FEI	Business Operations
Discus Dental, LLC		831726109	manufacture(64854-044)

Revised: 12/2021

Discus Dental, LLC