ZYLAST XP ANTISEPTIC- benzethonium chloride lotion Bocchi Laboratories 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.

Zylast Antiseptic Lotion Drug Facts

Active Ingredients

Benzethonium Chloride - 0.20%

Purpose

Antiseptic

Uses

- Handwash to decrease bacteria on the skin that potentially can cause disease.
- Recommended for repeated use.

Warnings

- For external use only.
- Avoid contact with eyes. In case of eye contact, rinse thoroughly with water.
- Discontinue use if irritation and redness develops. Consult a doctor if condition persists for more than 72 hours.
- If swallowed, immediately call Poison Control Center or doctor.

Directions

• Wet hands thoroughly with product and allow to dry without wiping.

Other Information

Store at 20-25°C (68-77°F)

Inactive ingredients

Water, Alcohol Denat., Cetearyl Alcohol, Glycerin, Polyaminopropyl Biguanide, Dimethicone, Stearamidopropyl Dimethylamine, Benzyl Alcohol, Farnesol, Panthenol, Zinc Gluconate, Chlorhexidine Digluconate, Citric Acid, Polyquaternium-10, Tocopheryl Acetate.

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Package/Label Principal Display Panel

NDC 57702-465-14 Zylast XP Extended Protection Broad Spectrum Antimicrobial Antiseptic 1000mL (33.8oz)

Drug Facts

Active Ingredients

Purpose

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Kills 99.99% of germs NDC: 57702-465-14

NON-IRRITATING, WATER BASED

1000mL (33.8oz)





Package/Label Principal Display Panel

NDC 57702-465-04 Zvlast XP Extended Protection **Broad Spectrum** Antimicrobial Antiseptic 8 fl oz. 236.6 mL



Drug Facts

Active Ingredients

Purpose

Benzethonium Chloride - 0.20% Antiseptic

Uses

- Handwash to decrease bacteria on the skin that potentially can cause disease.
- Recommended for repeated use.

Warnings

■ For external use only. ■ Avoid contact with eyes. In case of eye contact, rinse eyes thoroughly with water.

Discontinue use if irritation and redness develops. Consult a doctor if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, immediately call Poison Control Center or doctor.

Directions

■ Wet hands thoroughly with product and allow to dry without wiping.

Other Information

Store at 20-25°C (68-77°F)

Inactive Ingredients Water, Alcohol Denat., Cetearyl Alcohol, Glycerin, Polyaminopropyl Biguanide, Dimethicone, Stearamidopropyl Dimethylamine, Benzyl Alcohol, Farnesol, Panthenol, Zinc Gluconate, Chlorhexidine Digluconate, Citric Acid, Polyquaternium-10, Tocopheryl Acetate.

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Package/Label Principal Display Panel

NDC 57702-465-01 Zylast XP **Extended Protection Broad Spectrum**



Drug Facts

Active Ingredients

Purpose

Benzethonium Chloride - 0.20% Antiseptic

Uses ■ Handwash to decrease bacteria on the skin that potentially can cause disease. ■ Recommended for repeated use.

Warnings ■ For external use only. ■ Avoid contact with eyes. In case of eye contact, rinse eyes thoroughly with water. ■ Discontinue use if irritation and redness develops. Consult a doctor if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, immediately call Poison Control Center or doctor.

Directions ■ Wet hands thoroughly with product and allow to dry without wiping.

Other Information ■ Store at 20-25°C (68-77°F)

Inactive Ingredients Water, Alcohol Denat., Cetearyl Alcohol, Glycerin, Polyaminopropyl Biguanide, Dimethicone, Stearamidopropyl Dimethylamine, Benzyl Alcohol, Farnesol, Panthenol, Zinc Gluconate, Chlorhexidine Digluconate, Citric Acid, Polyquaternium-10, Tocopheryl Acetate.

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ZYLAST XP ANTISEPTIC

benzethonium chloride lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57702-465	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety	Active	Ingre	die nt/	Active	Moiety
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Ingredient Name Basis of Strength Strength

BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM -	
IINII:1\(\text{III}\) 1\(\text{III}\) 1\(\text	

BENZETHONIUM CHLORIDE

2 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLIHEXANIDE (UNII: 322U039GMF)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
STEARAMIDO PRO PYL DIMETHYLAMINE (UNII: K7VEI00 UFR)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
FARNESOL (UNII: EB41QIU6JL)			
PANTHENOL (UNII: WV9CM0O67Z)			
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)			
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:57702-465-01	59.1 mL in 1 BOTTLE			
2	NDC:57702-465-04	236.6 mL in 1 BOTTLE			
3	NDC:57702-465-14	1000 mL in 1 BOTTLE			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part333E	06/01/2011			

Labeler - Bocchi Laboratories Inc. (078376306)

Revised: 3/2014 Bocchi Laboratories Inc.