

HAND PROTECTOR- benzalkonium chloride solution

Cytonix, 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.

Benzalkonium Chloride 0.13%

Purpose: Antiseptic. Hand and skin sanitizer.

USES: to reduce bacteria on skin that could cause disease. Recommended for repeat use.

WARNINGS

For external use only.

Do not use in eyes.

When using this product avoid contact with eyes. In case of eye contact flush with water. Stop use and ask doctor if irritation and redness develop.

Keep out of reach of children.

If swallowed, get medical attention or contact a Poison Control Center.

Keep out of reach of children.

Avoid contact with eyes. In case of eye contact flush with plenty of water.

Stop use and ask doctor if irritation or redness develop.

3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride, Ethyl Alcohol, Water

Apply liberally to hands and gently rub until dry. Reapply after 4 hours.

Contact:

Cytonix LLC, Beltsville, MD

20705 USA 301-470-6267

www.cytonix.com

Hand Protector label 79291-653-03 16oz (473mL)

CYTONIX

HAND PROTECTOR



Drug Facts

| Active Ingredient | Purpose |
|-----------------------------|------------|
| Benzalkonium Chloride 0.13% | Antiseptic |

Uses To reduce bacteria on skin that could cause disease. Recommended for repeat use.

Warnings

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Directions

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Inactive Ingredients

Ethyl Alcohol, 3-(Trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride, Water.

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HAND PROTECTOR

benzalkonium chloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79 29 1-653 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------------|
| WATER (UNII: 059QF0KO0R) | 84 g in 100 mL |

Packaging

Marketing Start Marketing End

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79291-653-01 | 120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 07/01/2020 | |
| 2 | NDC:79291-653-02 | 473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 07/31/2020 | |
| 3 | NDC:79291-653-03 | 473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 07/31/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 07/01/2020 | |

Labeler - Cytonix, LLC (831532705)

Registrant - Elaine Lanza (831532705)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| Cytonix, LLC | | 831532705 | manufacture(79291-653) |

Revised: 9/2020

Cytonix, LLC