SEREN GUARD- sanitizing wipes patch Prime Pace Products 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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

- *Uses* Hand Sanitizer to decrease bacteria on skin.
 - Recommended for repeated use.

Warnings

For external use only.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Discontinue use if irritation and redness develop. If the condition persists for more than 72 hours, consult a Physician.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Thoroughly wipe hands as desired.

- Allow to dry without wiping.
- Discard wipe after use.
- Do not flush.

Other Information

- Keep sealed and store between 0-30°C (32 86°F)
- For External Use Only. Avoid sun exposure and excessive heat above 40°C

Inactive ingredients

Inactive Ingredients

Aqua, Propylene Glycol, Tocopheryl Acetate, Polysorbate 20, Phenoxyethanol.

Package Label - Principal Display Panel

SEREN GUARD 80

WIPES

Alcohol Free Skin friendly Ingredients

SEREN GUARD 80

WIPES

Sanitizing Wipes

STERILIZATION RATE 99.9%

USAGE

Click open the lid and peel back the resealable label.

Pull a sterilized wipe for sanitizing hands.

Reseal label after use to prevent the wipes from drying.

Batch No: Printed on bag.

Distributed By: Prime Pace Products LLC, 36181 East Lake Rd, Suite 302, Palm Harbor, FL 34685,

USA

Toll Free Number: 866-518-1984

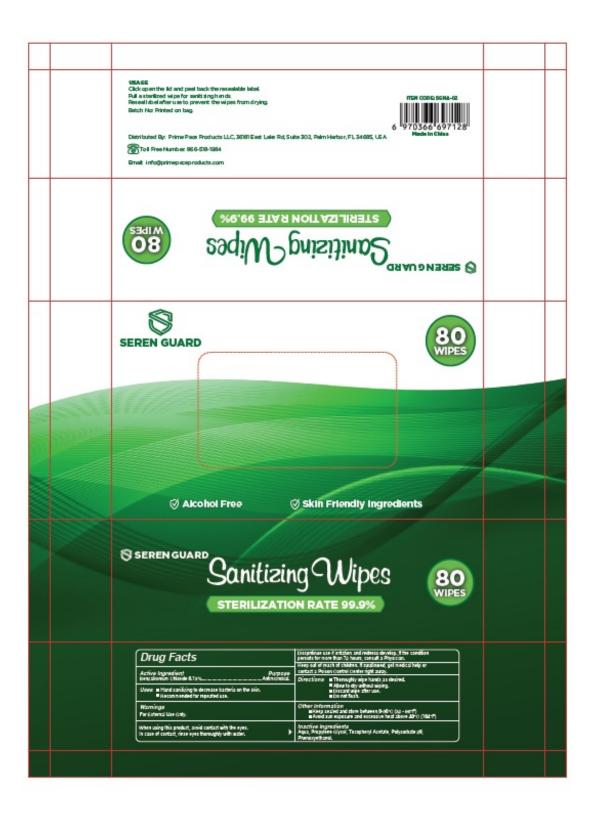
Email: info@primepaceproducts.com

ITEM CODE: SGNA-02

6 970366 697128

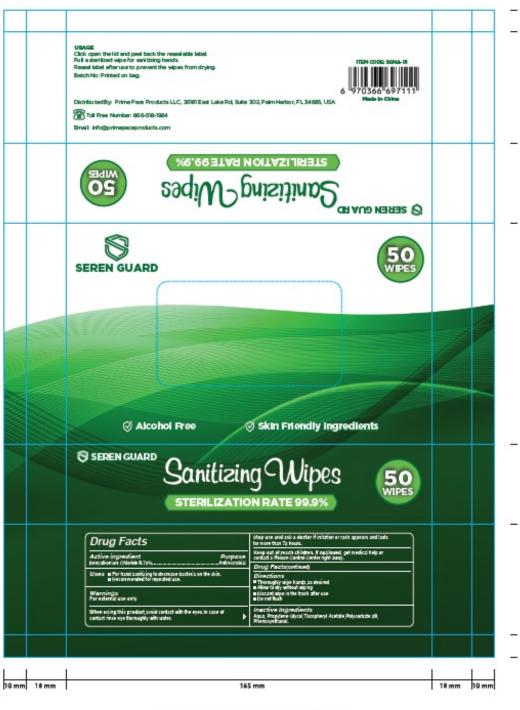
Made in China

80 Wipes













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SEREN GUARD

sanitizing wipes patch

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79183-001 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|---|--------------------------|--------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 g | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3) | |
| .ALPHATO COPHERO L ACETATE (UNII: 9E8 X80 D2L0) | |
| POLYSORBATE 20 (UNII: 7T1F30 V5YH) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

| P | Packaging | | | | |
|---|------------------|---|-----------------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:79183-001-80 | 80 in 1 BAG | 06/23/2020 | | |
| 1 | | 4.9 g in 1 PATCH; Type 0: Not a Combination Product | | | |
| 2 | NDC:79183-001-50 | 50 in 1 BAG | 06/23/2020 | | |
| 2 | | 4.9 g in 1 PATCH; 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 | part333A | 06/23/2020 | | |
| | | | | |

Labeler - Prime Pace Products LLC (081214185)

Registrant - Prime Pace Products LLC (081214185)

Revised: 12/2020 Prime Pace Products LLC