

SEREN GUARD SANITIZING WIPES- 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.

SEREN GUARD Sanitizing Wipes

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

- Hand sanitizing to decrease bacteria on the skin.
- Recommended for hand sanitizing use.

Warnings

For external use only.

When using this product, avoid contact with the eyes.
In case of contact, 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 below 0-30°C (32-38°F)
- Avoid sun exposure and excessive heat above 40°C (104°F)

Inactive Ingredients

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

Package Label - Principal Display Panel

80
COUNT

SEREN GUARD

Sanitizing Wipes

STERILIZATION RATE 99.9%

HYGIENIC STERILIZATION FOR HEALTH CARE

Alcohol Free

Skin Friendly Ingredients

Alcohol Free

STORAGE

Store in a cool and dry place.

Avoid direct sunlight.

DIRECTIONS

- Turn the cap counter clockwise to remove and peel off the seal.
- Gently tug at the center wipe and feed it through the cap from the inside out.
- Screw the cap back on and you are ready to use. Tilt to remove wipe one at a time.

Skin friendly ingredients.

ITEM CODE : SGNA-05

MATERIAL: NON-WOVEN

WIPES SIZE: 15X20CM

WIPES: 80 SHEET COUNT

Batch No: Printed on side.

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

Made in China

80 Count

Drug Facts

Active Ingredients	Purpose
Benzalkonium Chloride 0.12% Benzalkonium Chloride 0.12% Benzalkonium Chloride 0.12%	Antiseptic
Uses	• Hand sanitizing to decrease bacteria on the skin. • Disinfectant for food contacting area.
Warnings	For General Use Only.
When using this product, avoid contact with the eyes.	• In case of contact, rinse eyes thoroughly with water.
Directions	• Use for hand sanitizing and surface disinfection. If for sensitive individuals, use for 10-15 seconds, avoid a 10-second.
Keep out of reach of children. If cap missed, get medical help at contact. A warning center can help (800) 368-6777.	
Directions	• Thoroughly wipe hands to desired. • Allow to air-dry naturally. • Do not use after use. • Do not reuse.
Other information	• Keep sealed and dry below 80°F (26.7°C). • Avoid sun exposure and excessive heat above 80°F (26.7°C).
Inactive ingredients	• Water, Propylene Glycol, Triethylamine, Polyethylene Glycol, Phosphoric Acid.

80 COUNT

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Sanitizing Wipes

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Alcohol Free

Skin Friendly Ingredients

80 COUNT

STORAGE
Store in a cool and dry place. Avoid direct sunlight.

DIRECTIONS

1. Turn the cap counter clockwise to remove and peel off the seal.
2. Gently tug at the center wipe and feed it through the cap from the inside out.
3. Screw the cap back on and you are ready to use. Tilt to remove wipe one at a time.

CAUTION

- The cap should be immediately sealed after a wipe is removed, to prevent the volatilization of the disinfectant liquid on the wipe.
- This is a topical disinfectant product so keep the cap sealed to avoid contact with skin.
- Use one wipe per subject to avoid cross contamination.
- Disinfectant should be wiped and washed and then dried to water before use.

160 Count

200 Count

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SEREN GUARD SANITIZING WIPES

sanitizing wipes patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 183-40 1
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 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 183-401-08	80 in 1 BOTTLE, DISPENSING	07/30/2020	
1		4.9 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:79 183-401-16	160 in 1 BOTTLE, DISPENSING	07/30/2020	
2		4.9 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:79 183-401-20	200 in 1 BOTTLE, DISPENSING	07/30/2020	
3		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	07/30/2020	

Labeler - Prime Pace Products LLC (081214185)**Registrant** - Prime Pace Products LLC (081214185)

Revised: 12/2020

Prime Pace Products LLC