AKTIVE SANITIZING WIPES- ethanol alcohol 75% swab Gertex Hosiery

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.

Aktive Sanitizing Wipes

Active Ingredient

Ethanol Alcohol 75%

Purpose

Sanitize

Uses

Sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

For External use only. Flammable. Keep away from heat or flame.

Do not use

On children less than 2 months old of age

On open skin wounds

When using this product

Keep out of eyes, ears, mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor.

If irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- -Wet area thoroughly with wipe. Allow to dry without rinsing.
- -Supervise children under 6 years of age when using this product.

Other Information

Store at room temperature 15-30C (59-86F).

Avoid freezing and excessive heat above 40C (104 F)

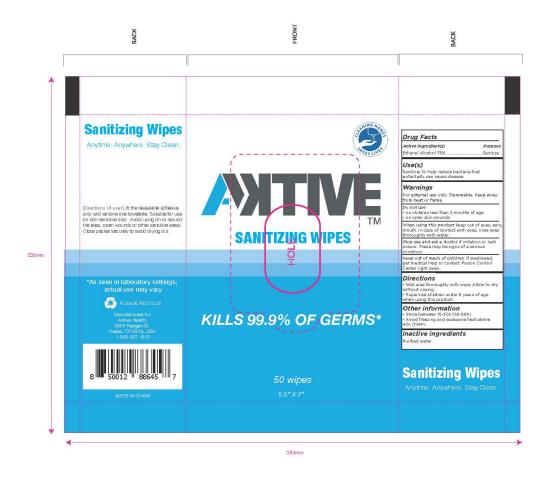
Inactive Ingredients

Purified Water

Aktive Sanitizing Wipes

PACKAGING ARTWORK:





AKTIVE SANITIZING WIPES

ethanol alcohol 75% swab

| Product Information | | | | |
|---------------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78164-100 | |
| Route of Administration | TOPICAL | | | |
| | | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |

Basis of Strength

Strength

Ingredient Name

| ALCOHOL | (UNII: 3K9958V90M) | (ALCOHOL - UNII:3K9958V90M) |
|---------|--------------------|-----------------------------|
|---------|--------------------|-----------------------------|

ALCOHOL

0.75 mL

| Inactive | Ingredients |
|-----------------|--------------------|
|-----------------|--------------------|

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

WATER (UNII: 059QF0KO0R)

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:78164- 100-50 | 50 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 2 | NDC:78164- 100-05 | 5 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 3 | NDC:78164- 100-10 | 10 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 4 | NDC:78164- 100-25 | 25 in 1 POUCH; Type 0: Not a Combination Product | 05/01/2020 | | |
| 5 | NDC:78164- 100-30 | 30 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 6 | NDC:78164- 100-40 | 40 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 7 | NDC:78164- 100-75 | 75 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 05/01/2020 | | |
| 8 | NDC:78164- 100-80 | 80 in 1 POUCH; Type 0: Not a Combination Product | 05/01/2020 | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 05/01/2020 | | |
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Labeler - Gertex Hosiery (201658481)

Registrant - Gertex Hosiery (201658481)

Revised: 5/2020 Gertex Hosiery