

ANTIBACTERIAL WIPES- benzalkonium chloride cloth
Zhejiang Yiwu Anrou Sanitation Article Co., Ltd

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.

Anrou-PGM, Antibacterial wipes, Benzalkonium Chloride

ACTIVE INGREDIENT

Benzalkonium Chloride, 0.11875%

Cereals Extraction Extract, 0.05%

2-Phenoxyethanol, 0.02025%

2-Methy-4-isothiazolin-3-one, 0.00625%

Iodopropynyl Butylcarbamate, 0.00225%

Purpose

Antibacterial

WARNINGS

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

Do not use

On children less than 2 years of age, or on open skin wounds.

STOP USING AND ASK 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 Poison Control Center right away.

Use

Sanitizing Wipe helps to reduce bacteria & virus that can potentially cause disease.

For use when soap & water are not available.

DIRECTIONS

Store in a cool and dry place.

Remove cover.

Pull up wipe corner from center of roll.

Thread through hole in the cover.

Replace cover.

Open center cap on cover to remove wipe.

When not using, close center cap securely to prevent moisture loss.

Reseal and let hands dry.

No need to rinse.

CAUTION

WARNING FLAMMABLE

Keep away from heat, spark, electrical, fire or flame.

Store in a cool and dry place.

INACTIVE INGREDIENT

1,2-Propanediol

Water

Package label. Principal display panel



11.5cm x 30cm

SANTA FE WIPES

ANTIBACTERIAL WIPES

STERILIZATION RATE 99.9%

80 WIPES

- KILLS 99.9% OF GERMS
- DRIES FAST

ACTIVE INGREDIENT: Benzalkonium Chloride 0.1875%;
Cereals extraction extract 0.05%;
2-Phenoxyethanol 0.0025%;
2-Methyl-4-isothiazolin-3-one 0.00625%;
Lodopropynyl butylcarbamate 0.0025%;

INACTIVE INGREDIENT: 1,2-Propanediol 0.075% - Other ingredients 99.725%

Use: Sanitizing Wipe helps to reduce bacteria & virus that can potentially cause disease. For use when soap & water are not available.

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

STOP USING AND ASK 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 Poison Control Center right away.

DIRECTIONS: Store in a cool and dry place. Remove cover. Pull up wipe corner from center of roll. Thread through hole in the cover. Replace cover. Open center cap on cover to remove wipe. When not using, close center cap securely to prevent moisture loss. Reseal and let hands dry. No need to rinse.

CAUTION

WARNING FLAMMABLE

Keep away from heat, spark, electrical, fire or flame.

Do not use: On children less than 2 years of age, or on open skin wounds.

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ITEM#PG64024

MADE IN CHINA

Distributed by PGM GROUP
Santa Fe Springs, California

ANTIBACTERIAL WIPES

benzalkonium chloride cloth

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78 356-211 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|-----------------------------|-----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 5 mg |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) (METHYLISOTHIAZOLINONE - UNII:229D0E1QFA) | METHYLISOTHIAZOLINONE | 0.2625 mg |
| BARLEY (UNII: 5PWM7YL17R) (BARLEY - UNII:5PWM7YL17R) | BARLEY | 2.1 mg |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T) | PHENOXYETHANOL | 0.84 mg |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) (IODOPROPYNYL BUTYLCARBAMATE - UNII:603P14DHEB) | IODOPROPYNYL BUTYLCARBAMATE | 0.0945 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78356-211-21 | 80 in 1 PAIL; Type 0: Not a Combination Product | 08/06/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/06/2020 | |

Labeler - Zhejiang Yiwu Anrou Sanitation Article Co., Ltd (547950139)

Registrant - A03 Lab of BTS (548009541)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---|
| Zhejiang Yiwu Anrou Sanitation Article Co., Ltd | | 547950139 | manufacture(78356-211) , label(78356-211) |

Revised: 8/2020

Zhejiang Yiwu Anrou Sanitation Article Co., Ltd