# PANROSA ALCOHOL-FREE HAND SANITIZER WITH REFRESHING ALOE DUAL ACTION MOISTURIZERS- benzalkonium chloride gel Panrosa Enterprises, Inc.

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.

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#### PANROSA Alcohol-Free Hand Sanitizer with Refreshing Aloe Dual Action Moisturizers

#### **Drug Facts**

#### Active ingredients

Benzalkonium Chloride 0.13%

#### **Purpose**

Antibacterial

#### Uses

- hand sanitizer to help decrease bacteria on the skin, when water, soap & towel are not available.
- recommended for repeated use.

#### **Warnings**

For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.

#### Do not use

in ears & mouth.

#### When using this product,

avoid contact with eyes. In case of contact flush eyes with water.

#### Stop use and ask a doctor if

redness or irritation develop and persist for more than 72 hours.

#### Keep out of reach of children.

Children must be supervised in use of this product.

#### Directions

- pump as needed into your palms and thoroughly spread on both hands.
- rub into skin until dry.

#### Other information

- store at 20°C (68°F to 77°F).
- may discolor fabrics.

#### **Inactive ingredinets**

WATER, HYDROXYETHYLCELLULOSE, BIS-PEG-18 METHYL ETHER DIMETHYL SILANE, PEG-40 HYDROGENATED CASTOR OIL, DISODIUM EDTA, FRAGRANCE, ALOE BARBADENSIS JUICE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE.

#### Package Labeling:50302-12-50





Package Labeling:50302-12-23



### Drug Facts

### Active ingredients

Benzalkonium Chloride 0.13%....

Purpose Antibacterial

**Uses** • hand sanitizer to help decrease bacteria on the skin, when water, soap & towel are not available. • recommended for repeated use.

Warnings For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes. Do not use in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

**Directions** • pump as needed into your palms and thoroughly spread on both hands. • rub into skin until dry.

**Other information** ■ store at 20°C (68°F to 77°F). ■ may discolor fabrics.

Inactive ingredients water, hydroxyethylcellulose, bis-peg-18 methyl ether dimethyl silane, peg-40 hydrogenated castor oil, disodium edta, fragrance, aloe barbadensis leaf juice, methylchloroisothiazolinone, methylisothiazolinone.

PANROSA ENTERPRISES, INC.

550 Monica Circle, Corona, CÁ 92880 www.panrosa.com



Package Labeling:59ml



# Drug Facts

# Active ingredients

Purpose

Benzalkonium Chloride 0.13%.....

.Antibacterial

 Uses • hand sanitizer to help decrease bacteria or the skin, when water, soap & towel are not available.
recommended for repeated use.

## Warnings For external use only.

Flammable. Keep away from fire or flame.

**Do not apply around eyes. Do not use** in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

**Keep out of reach of children.** Children must be supervised in use of this product.

**Directions** • pump as needed into your palms and thoroughly spread on both hands. • rub into skin until dry.

Other information ■ store at 20°C (68°F to 77°F). ■ may discolor fabrics.

Inactive ingredients WATER, HYDROX-YETHYLCELLULOSE, BIS-PEG-18 METHYL ETHER DIMETHYL SILANE, PEG-40 HYDROGE-NATED CASTOR OIL, DISODIUM EDTA, FRAGRANCE, ALOE BARBADENSIS LEAF JUICE, METHYLCHLOROISOTHIAZOLINONE, METHYLI-SOTHIAZOLINONE.

### PANROSA ENTERPRISES, INC.

550 Monica Circle, Corona, CÁ 92880 www.panrosa.com



Package Labeling: 118ml



# **Drug Facts**

Active ingredients

Purpose

Benzalkonium Chloride 0.13%.....

.. Antibacterial

Uses ■ hand sanitizer to help decrease bacteria on the skin, when water, soap & towel are not available. ■ recommended for repeated use.

Warnings For external use only.

Flammable. Keep away from fire or flame.

**Do not apply around eyes. Do not use** in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

**Keep out of reach of children.** Children must be supervised in use of this product.

**Directions** • pump as needed into your palms and thoroughly spread on both hands. • rub into skin until dry.

**Other information** ■ store at 20°C (68°F to 77°F). ■ may discolor fabrics.

Inactive ingredients water, hydroxyethylcellulose, bis-peg-18 methyl ether dimethyl silane, peg-40 hydrogenated castor oil, disodium edta, fragrance, aloe barbadensis leaf juice, methylchloroisothiazolinone, methylisothiazolinone.

PANROSA ENTERPRISES, INC. 550 Monica Circle, Corona, CA 92880 www.panrosa.com



benzalkonium chloride gel

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:50302-012 |
| Route of Administration | TOPICAL        |                    |               |

| l | Active Ingredient/Active Moiety                                                       |                          |                   |  |
|---|---------------------------------------------------------------------------------------|--------------------------|-------------------|--|
| l | Ingredient Name                                                                       | Basis of Strength        | Strength          |  |
|   | <b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y) | BENZALKONIUM<br>CHLORIDE | 1.3 mg<br>in 1 mL |  |

| Inactive Ingredients                                       |          |  |
|------------------------------------------------------------|----------|--|
| Ingredient Name                                            | Strength |  |
| WATER (UNII: 059QF0KO0R)                                   |          |  |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)     |          |  |
| BIS-PEG-18 METHYL ETHER DIMETHYL SILANE (UNII: OEB4R3WW9C) |          |  |
| POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)     |          |  |
| EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)         |          |  |
| METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)         |          |  |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)                 |          |  |

| P | Packaging        |                                                       |                             |                           |
|---|------------------|-------------------------------------------------------|-----------------------------|---------------------------|
| # | Item Code        | Package Description                                   | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 | NDC:50302-012-50 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/13/2020                  |                           |
| 2 | NDC:50302-012-23 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/13/2020                  |                           |
| 3 | NDC:50302-012-59 | 59 mL in 1 TUBE; Type 0: Not a Combination Product    | 04/30/2020                  |                           |
| 4 | NDC:50302-012-18 | 118 mL in 1 TUBE; Type 0: Not a Combination Product   | 04/30/2020                  |                           |

| Marketing Information   |                                          |                      |                    |
|-------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333E                                 | 04/13/2020           |                    |
|                         |                                          |                      |                    |

# Labeler - Panrosa Enterprises, Inc. (859957578)

Revised: 7/2020 Panrosa Enterprises, Inc.