

ARIAS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Scentials Beautycare And Wellness Private Limited

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.

ARIAS® ANTISEPTIC HAND SANITIZER GEL

Drug Facts

Active ingredient

Ethyl alcohol 72% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)

- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

water, glycerin, diethylphthalate, carbomer, fragrance, triethanolamine, tocopherol acetate, aloe vera extract

Questions?

+1-917- 719-0285

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM

LARA DUTTA

REFRESHING GEL

With Moisturizers, Vitamin E & Aloe Vera Extract

Distributed By: SCENTIALS BEAUTYCARE & WELLNESS PVT. LTD.

1001/1002, LOTUS GRANDEUR, OFF VEERA DESAI ROAD, ANDHERI WEST,
MUMBAI 400053, INDIA.

MADE IN INDIA

care@scentialsworld.com

www.scentialsworld.com

scentials_world @scentialsworld

Arias is the registered trademark of Arias Branding LLP.

Imitation of Graphics/Pack Design is a punishable offence.

Packaging

ARIAS[®]
LARA DUTTA



**ANTISEPTIC
HAND
SANITIZER GEL**

REFRESHING GEL

With Moisturizers, Vitamin E & Aloe Vera Extract

16.91 fl oz (1 pt 0.91 fl oz) (500 mL)

Drug Facts

| Active ingredient | Purpose |
|----------------------------|------------|
| Ethyl alcohol 72% v/v..... | Antiseptic |

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/ flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information


- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients water, glycerin, diethyl phthalate, carbomer, fragrance, triethanolamine, tocopherol acetate, aloe vera extract

Questions? +1-917-719-0285
You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM

Distributed By: SCENTIALS BEAUTY CARE & WELLNESS PVT. LTD.
1001/1002, LOTUS GRAND BLDG, OFF VEERA DESAI ROAD, ANDHERI WEST,
MUMBAI 400053, INDIA.

MADE IN INDIA care@scentialsworld.com
www.scentialsworld.com



76603-100-50

XXXX-XX-XXXX
XXX-XXX-XXXX

ARIAS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76603-100 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 72 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DIETHYL PHTHALATE (UNII: UF064M00AF) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:76603-100-03 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 2 | NDC:76603-100-05 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 3 | NDC:76603-100-06 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 4 | NDC:76603-100-10 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 5 | NDC:76603-100-25 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 6 | NDC:76603-100-30 | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |
| 7 | NDC:76603-100-50 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333A | 05/15/2020 | |

Labeler - Scentials Beautycare And Wellness Private Limited (861188203)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| S.P.Y. AGRO INDUSTRIES LIMITED | | 676197931 | manufacture(76603-100) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|------------------------|
| Guangzhou Zuofun Cosmetics Co., Ltd | | 530135094 | manufacture(76603-100) |

Revised: 7/2020

Scentials Beautycare And Wellness Private Limited