

**ABBEXA HAND SANITIZER- ethanol gel**  
**ABBEXA 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.*

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**Abbexa Hand Sanitizer Gel**

***Product Information***

***Active Ingredient***

Ethanol 75%

***Purpose***

Antiseptic

***Use*** To sterilize and disinfect skin.

***Warnings*** For external use only.

**FLAMMABLE** liquid and vapour. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Causes serious eye irritation. Keep container tightly closed.

**Avoid contact with eyes.** If contact occurs, immediately rinse eyes with water. **Stop use and consult a doctor** if irritation and redness persists.

**Keep out of reach of children.** If swallowed, seek medical assistance.

***Directions*** Apply evenly to hands, then repeatedly rub hands until product has dried. No water required. Do not use on damaged, sensitive or irritated skin. In case of contact, rinse thoroughly with tepid water.

***Other Information*** Proven to be effective at decreasing bacteria. Suitable for repeated use on skin.

This product contains ethanol, which can irritate mucous membranes and wounds, and should not be used by those who are allergic to alcohol.

***Storage*** Do not store above 110°F (43 °C).

***Inactive Ingredients*** Carbomer, Glycerol, Rose Essence, Distilled Water, Triethanolamine.

**Rinse-Free**

**Quick Drying**

**Antibacterial**

Abbexa LTD, Cambridge, UK, CB4 0GJ

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Abbexa LLC, Houston, TX, USA, 77042

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**Packaging**

abbexa 

abbexa 

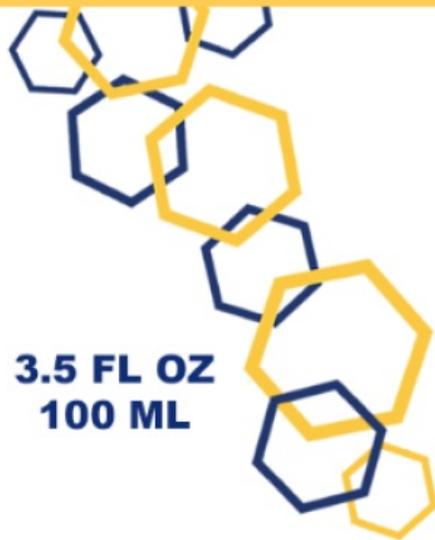


**Hand Sanitizer Gel**

**Rinse-Free Quick Drying**

**Antibacterial**

**3.5 FL OZ  
100 ML**



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|-------------------|------------|
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abx091010



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v2004a · Lot: abx091010 · EXP: 04/2022

**ABBEXA HAND SANITIZER**

ethanol gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:74029-100 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 75 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                |          |
| WATER (UNII: 059QF0KO0R)                                   |          |
| TROLAMINE (UNII: 9O3K93S3TK)                               |          |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74029-100-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 04/02/2020           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 04/02/2020           |                    |

**Labeler** - ABBEXA LTD (219351130)

## Establishment

| Name       | Address | ID/FEI    | Business Operations    |
|------------|---------|-----------|------------------------|
| ABBEXA LTD |         | 219351130 | manufacture(74029-100) |

Revised: 4/2020

ABBEXA LTD