80 ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER- alcohol liquid SCHEVARAN LABORATORIES 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.

80% Ethyl Alcohol Antiseptic Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 80%

Purpose

Antiseptic

Use

for hand washing to decrease bacteria on the skin

Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use

in the eyes

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.

Inactive ingredients

Hydrogen peroxide, glycerin, FD&C Blue No. 1, fragrance

Questions?:

+1-716-430-3572

Package Labeling:



80 ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER

alcohol liquid

| Product Information | | | |
|----------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82444-001 |
| Route of Administration | TOPICAL | | |
| | | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|-----------------|
| Ingredient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |
| | | |

| Inactive Ingredients | | | |
|--------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | |

| l | P | Packaging | | | |
|---|---|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:82444-001- 00 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/30/2022 | |

| Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333E | 06/30/2022 | |
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Labeler - SCHEVARAN LABORATORIES PRIVATE LIMITED (650656770)

Revised: 3/2022 SCHEVARAN LABORATORIES PRIVATE LIMITED