**ANATIZER GEL 75% ETHANOL- ethanol gel gel**
**Anat Incorporated**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a 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 a Poison Control Center right away.

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away.

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

ANATIZER™

# HAND SANITIZER

**KILLS HARMFUL GERMS AND BACTERIA**

a natural sanitizer

**RECOMMENDED USE:** Kills harmful bacteria and germs.
**DIRECTION FOR USE:** Adults 18 years and older; For occasional and personal domestic use, Rub thoroughly into hands for at least 30 seconds. Allow to dry.
**MEDICINAL INGREDIENTS:** Ethyl Alcohol 75%
**NON-MEDICINAL INGREDIENTS:** Glycerin, Hydrogen Peroxide, Hydroxy Ethyl Cellulose, Water. This product does not contain mercury.
**WARNING:** Adults only; Do not use on broken or damaged skin; Do not use if you are pregnant or breastfeeding; Do not inhale; For external use only; Keep out of reach of children; If swallowed, call a poison control centre or get medical help right away; Stop use and ask/consult a doctor/physician/healthcare practitioner/healthcare provider/healthcare professional if irritation develops; When using this product avoid contact with eyes, if contact occurs, rinse thoroughly with water.
**FLAMMABILITY WARNING:** Keep away from open flame and source of heat.
**STORAGE CONDITION:** Between 59-86˚F.

**Manufactured by Anat Inc.**
101 Toro Rd. Unit 5, Toronto, Canada M3J 2Z1

**33.8 fl oz (1 L)**
*75% alcohol*

NDC 75171-111-10

LOT# AN012 EXP MA 2023

## ANATIZER GEL 75% ETHANOL

ethanol gel gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:75171-222 |
| **Route of Administration** | 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** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:75171-222-40 | 3780 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/24/2020 | |
| **2** | NDC:75171-222-10 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/24/2020 | |
| **3** | NDC:75171-222-03 | 234 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/24/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 08/24/2020 | |

## Labeler - Anat Incorporated (243784795)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Anat Incorporated | | 243784795 | manufacture(75171-222) |

Revised: 1/2021 Anat Incorporated