SANITIZING ISOPROPYL ALCOHOL WIPES- hand sanitizer cloth
Unitrex 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.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Isopropyl alcohol Antiseptic Wipes 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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Directions

- Wipe the surface of the skin with a damp paper towel until it is dry. Do not rinse with water immediately after wiping.
- 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

purified water USP

Package Label - Principal Display Panel

80 Wipes NDC: 78553-3920-1

SANITIZING ISOPROPYL ALCOHOL WIPES

hand sanitizer cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78553-3920
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	25 g in 100 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78553-3920-1	370 g in 1 CAN; Type 0: Not a Combination Product	08/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	08/27/2020	

Labeler - Unitrex Ltd. (062032343)

Registrant - Unitrex Ltd. (062032343)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Wellbeing Technology Co., Ltd.		414010999	manufacture(78553-3920)

Revised: 8/2020 Unitrex Ltd.