PYURX- disinfectant wet wipes cloth
Novara LLC

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.

75% Alcohol Disinfectant Wet Wipes. 50 count

Active Ingredient(s)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizing

Use

- For hand sanitizing to decrease bacteria on skin.
- Recommened for repeated use.

Warnings

- Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.
- Do not use on children less than 2 months of age.
- For external use only.
- Flammable Keep away from heat or flame

Do not use

- Do not use in the eyes. In case of contact, rinse thoroughly with water.
- Do not use on children less than 2 months of age.

- Stop use and ask a doctor if irritation or redness develop and persist for more than 72 hours.
- Swallowed, get medical help or contact a poison control center right away.

Keep out of reach of children

- Children must be supervised when using this product.

Directions

- Wet hands thoroughly with product and allow to dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store at below or below 75F (24C).
- May discolor certain fabrics or surfaces.

Inactive ingredients

glycerin, Aqua(water), Vitamin E, Aloe

Package Label - Principal Display Panel

PYURX

disinfectant wet wipes cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80527-351
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)	0.3 mL in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.4 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80527-351-51	50 mL in 1 PACKAGE; Type 0: Not a Combination Product	09/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/21/2020	

Labeler - Novara LLC (117659846)

Establishment

Name	Address	ID/FEI	Business Operations
Novara LLC		117659846	relabel(80527-351)

Establishment

Name	Address	ID/FEI	Business Operations
NanTong Guarder Medical Technology Co.,Ltd.		554537961	manufacture(80527-351)

Revised: 2/2021 Novara LLC