

FIRST LINE ALCOHOL WIPES- alcohol cloth

PayDirt Gold Company, 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.

First Line Alcohol Wipes

Drug Facts

Active ingredient

Ethyl alcohol 75% v/v

Purpose

Antiseptic

Use

- Topical antiseptic
- Recommended for repeated use

Warnings

Flammable. Keep away from fire or flame.

For external use only.

Do not use

- in children less than 2 months in 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 redness develops and lasts more than 72 hours

Keep out of reach of children.

If swallowed, seek medical help or contact a Poison Control Center right away.

Directions

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

Other information

- Store between 15°-30°C (59°-86°F)
- Avoid freezing and excessive heat over 40°C (104°F)
- Protect from direct sunlight. Keep container sealed.
- May discolor certain fabrics or surfaces.

Inactive ingredients

water, glycerin

Package Labeling:



FIRST LINE ALCOHOL WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81043-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81043-001-01	70 in 1 CANISTER	10/01/2020	
1		3.8 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/01/2020	

Labeler - PayDirt Gold Company, LLC (062002474)

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PayDirt Gold Company, LLC