WIPES SOLUTIONS ANTISEPTIC WET WIPES- ethyl alcohol cloth Supplyclean Industria de Produtos de Higiene S/A

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.

WIPES SOLUTIONS ANTISEPTIC WET WIPES

Drug Facts

Active ingredient

Ethyl alcohol 73% v/v

Purpose

Antiseptic

Uses

- hand wipes to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

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

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

do not ingest

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

- remove the plastic cover and pull the tip of the first wipe in the center of the roll
- insert the tip of the scarf into the center opening of the cover from the bottom up
- replace the cap, pull the first wipe and the rest will come off automatically
- wipe hands thoroughly with product and allow to dry without wiping

- dispose of the wipe in the trash
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above (104°F)

Inactive ingredients water, propylene glycol

ALCOHOL 73%

HYDRATED ETHYL ALCOHOL

READ THE LABEL CAREFULLY BEFORE USING THE PRODUCT

Distributed by: Wipes Solutions Inc.

1728 NE Miami Gardens DR. Ste.209,

Miami, FL 33179

Made in Brazil

info@wipessolutions.com

Directions for use: Open the package and use the wet wipe After use, dispose of the wipe in the trash

DO NOT FLUSH

KEEP OUT OF THE REACH OF CHILDREN AND DOMESTIC ANIMALS

FLAMMABLE

keep away from fire and heat. Do not pierce the cover

Shelf life 24 months

/supplyclean

@supplyclean

Packaging



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Drug Facts (continued)

DrugFacts (continued)

Drug Facts



DRUG FACTS LABEL



WIPES SOLUTIONS ANTISEPTIC WET WIPES

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80310-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:80310-018-	8 35 in 1 TUBE	08/28/2020		
l	1	5.71 mL in 1 PACKAGE; Type 0: Not a Combination Product			
	2 NDC:80310-018- 36	150 in 1 PAIL	08/28/2020		
	2	3.66 mL in 1 PACKAGE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/28/2020		

Labeler - Supplyclean Industria de Produtos de Higiene S/A (944745857)

Establishment				
Name	Address	ID/FEI	Business Operations	
Supplyclean Industria de Produtos de Higiene S/A		944745857	manufacture(80310-018)	

Revised: 8/2020 Supplyclean Industria de Produtos de Higiene S/A