

LUBRIMA ALCOHOL WET WIPES- ethyl alcohol cloth
AGRO GRUP TEKNOLOJI BILGISAYAR SISTEMLERI TEMIZLIK MADDELERI SANAYI
VE TICARET LIMITED SIR

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.

Lubrima ALCOHOL WIPES

Drug Facts

Active ingredient

Ethyl Alcohol (80%)

Purpose

Hand Sanitizing

Uses Do not use on eyes and mouth area, temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

Warnings

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

Do NOT dispose in toilet to avoid clogging. Keep in cool place indoors avoid high temperature and direct sunlight. Do NOT throw on fire.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of unexpected symptoms, get medical help or contact a poison Control Center right away.

Directions

Open the cover of the wet wipes or seal the sticker. After use please close the wet wipes cover or seal the sticker to keep the wet wipes moist.

adults and children 12 years and over	Use as directed
children 6 years to under 12 years	Use as directed
children under 6 years	ask a doctor

Other information

- store at 20-25° C (68-77° F)
- protect from excessive moisture

Inactive ingredients

Aqua, Glycerine

%80 ALCOHOL FORMULATION SAFE FOR HANDS

ALCOHOL CONTENT %80

WARNING

After use please close the seal to prevent water evaporation. Discontinue use if there is any wound, redness, swelling or other discomfort. Wet wipes do not dissolve in water.

PRODUCT FEATURES

Super thick soft cotton touch for increased comfort. Reverse osmosis purified water removes impurities.

Consignor:

A-K Health LLC

520 Robinson LN Unit 4, Wilmington

19805 DE (Delaware)

+1 857 272 4139

EIN: 35-2643785

ISO

GMP

PRODUCT INFORMATION

Name of Commodity: Hand wipes

Product Specification: 140mm x 200mm / 80 Pcs. / Net Weight: 425g / Gross Weight: 450g.

Name of Commodity: Hand wipes

Manufacturer: AGRO GRUP TEKNOLOJI LTD. STI.

Selimpasa Mah. 6093. sk. No: 86/1

Silivri / Istanbul - Türkiye

UBB Record Number: 0080856431

Man. Licence No: 27527096

Packaging



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ALCOHOL WIPES

%80 ALCOHOL FORMULATION SAFE FOR HANDS



80 PCS

140 x 200 mm

DRUG FACTS LABEL

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LUBRIMA ALCOHOL WET WIPES

ethyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80481-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80481-101-01	80 in 1 CANISTER	08/31/2020	
1		4.20 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
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OTC monograph not final	part333A	08/31/2020	
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Labeler - AGRO GRUP TEKNOLOJI BILGISAYAR SISTEMLERİ TEMİZLİK MADDELERİ SANAYİ VE TİCARET LİMİTED SİR (533148117)

Establishment

Name	Address	ID/FEI	Business Operations
AGRO GRUP TEKNOLOJI BILGISAYAR SISTEMLERİ TEMİZLİK MADDELERİ SANAYİ VE TİCARET LİMİTED SİR		533148117	manufacture(80481-101)

Revised: 9/2020

AGRO GRUP TEKNOLOJI BILGISAYAR SISTEMLERİ TEMİZLİK MADDELERİ SANAYİ VE TİCARET LİMİTED SİR