

BIOLUSTRE ALCOHOL WIPES- ethyl alcohol cloth
KOYUNCU BİLİŞİM TEKNOLOJİLERİ SANAYİ VE TİCARET LIMITED SİRKETİ

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.

Alcohol 70%

Water

Antiseptic

Used for antibacterial hand skin, prevent bacteria.

For external use only. Flammable. Keep away from fire.

- Keep away from fire.
- Do not wipe your eyes.
- Do not throw into the toilet (not soluble in water).
- Please wait until the alcohol has completely evaporated after wiping.
- Before use, check whether the packaging is intact. Do not use if it is damaged.

Stop use and ask a doctor for those with alcohol allergy or sensitive skin.

Keep out of reach of children.

- Store between 15-30°C (59-86°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Use it as needed, after following the usage instructions. For external use only.



BIOLUSTRE ALCOHOL WIPES

ethyl alcohol cloth

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80371-101

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80371-101-01	72 g in 1 POUCH; Type 0: Not a Combination Product	08/31/2020	
2	NDC:80371-101-02	100 g in 1 POUCH; Type 0: Not a Combination Product	08/31/2020	
3	NDC:80371-101-03	400 g in 1 POUCH; Type 0: Not a Combination Product	08/31/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		08/31/2020	

Labeler - KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI (505247089)

Registrant - KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI (505247089)

Establishment			
Name	Address	ID/FEI	Business Operations
KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI		505247089	manufacture(80371-101)