FRESH N SOFT ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI

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.

Fresh'n Soft® [antibacterial wet wipes

Drug Facts

Active Ingredients

Benzalkonium Chloride (0.1%)

Purpose

Antiseptic

Use

Decreases bacteria on the skin that could cause disease

Warnings

For external use only.

- **Do not** use as baby wipe.
- **Do not** use if you are allergic to any of the ingredients.
- **Do not** use on open skin wounds.

When using this products

- Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation or allergic reaction occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Gently open resealable label, remove and use wipes as required. Keep label closed to prevent moisture loss.
- No need to rinse after usage. Allow skin to dry without wiping. For adults and children 2 years and over. Discard properly after use. Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store in dry and cool place.
- Production date, expiry date and lot number are printed on the pack.

Inactive ingredients

water, phenoxyethanol, propylene glycol, parfum, cocamidopropyl betaine, peg-40 hydrogenated castor oil, benzoic acid, tetrasodium edta, dehydroacetic acid, sodium hydroxide

DERMATOLOGICALLY TESTED

EN 1276

KARDESLER

UCAN YAGLAR SANAYI A.S.

1957

MANUFACTURER KARDESLER UÇAN YAGLAR SANAYI A.S.

INÖNÜ MAHALLESI GEBZE PLASTIKÇILER OSB MAHALLESI 42.SOKAK NO:1 41400 GEBZE - KOCAELI - TÜRKIYE T +90 (0262) 751 29 30 www.kardeslerucanyaglar.com info@kardeslerucanyaglar.com

www.freshnsoft.com

FreshnSoft

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ISO 22716 Good Manufacturing Practices

ISO 9001 Quality Management System

EAC Made in Turkey.

Packaging

































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benzalkonium chloride cloth

Product Type HUMAN OTC DRUG Item Code (Source) NDC:86937-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength			
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:86937-005- 01	15 in 1 PACKET	12/23/2020		
1		2.688 g in 1 PACKAGE; Type 0: Not a Combination Product			
2	NDC:86937-005- 02	60 in 1 PACKET	12/23/2020		
2		3.192 g in 1 PACKAGE; Type 0: Not a Combination Product			
3	NDC:86937-005- 03	80 in 1 CANISTER	12/23/2020		
3		2.9792 g in 1 PACKAGE; Type 0: Not a Combination			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	12/23/2020			

Establishment					
Name	Address	ID/FEI	Business Operations		
KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI		644389322	manufacture(86937-005)		

Revised: 12/2020

KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI