

**ANTIBACTERIAL ANTISEPTIC WET WIPES- antibacterial antiseptic wet wipes cloth
PRISTINE MK 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.

PRISTINE MK ANTIBACTERIAL ANTISEPTIC WET WIPES 120 PCS

Active Ingredient(s)

Benzalkonium chloride 0.13% v/v ,

Purpose

Antiseptic, Wet Wipes

Use

decreases bacteria on skin For use when soap and water are not available

Warnings

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, ears and mouth ,If contact occurs, rinse thoroughly with water

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours. these may be signs of a serious condition

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

Directions

adults and children 2 years and over - apply to hands - wet hands thoroughly with product and allow it to dry

Children under 2 years - ask a doctor before use

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat

Inactive ingredients

deionised water, Cetearyl isononanoate, Cetearth-20, Cetearyl alcohol, glyceryl stearate, glycerine, cetearth-12, cetyl-palmitate, phenoxyethanol, sodium benzoate, fragrance, citric acid,

disodium EDTA

Package Label - Principal Display Panel


120 WIPES

Pristine MK
Antibacterial Antiseptic Wet Wipes
are perfect for quick clean-ups when soap
and water are not available.
Use anytime, anywhere.



Drug Facts	Active Ingredient	Purpose
Use - decreases bacteria on skin. For use when soap and water are not available.	Chlorhexidine 0.13% W/V	Antibacterial
Warnings For external use only.		
Do not use - in children less than 2 months of age - in open wounds		
When using this product do not get into your eyes and do not use if contact lenses.		
Stop use and ask a doctor if irritation or rash develops and continues for more than 7 days. These may be signs of a serious condition.		
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away at 1-800-232-1222.		
Directions adults and children 2 years and over - apply to hands thoroughly with water and allow to dry		
children under 2 years - ask a doctor before use		
Directions for use - to disperse peel back front label slowly - remove wipes. - rub the moist firmly run thumb over the label - do not flush		
Other information - Store between 15-30C (59-86F) - Avoid freezing and excessive heat		
Inactive Ingredients water, propylene glycol, polyethylene glycol-200, coconut alcohol, glycerol stearate, glycerine, cetylalcohol, 1,2-cyclohexanediol, benzalkonium chloride, sodium EDTA, isopropyl alcohol, and benzalkonium chloride.		
Questions - 1 (702) 706 1657		

ITEM NO: BK256789
3 19 00 81 2 13 20 57 0

MANUFACTURED FOR:
PRISTINE MK L.L.C.
3595 East Patrick Lane, Suite 600
Las Vegas, NV 89120, USA.
www.pristinemk.com
Made in Kosovo, Europe.
Expiry date, LOT no. and NDC no.
printed on packaging.



Antibacterial Antiseptic wet wipes
trusted protection
Sanitizes thoroughly
120 PCS
pH balanced



Antibacterial antiseptic WET WIPES

KILLS 99.99% OF ILLNESS CAUSING GERMS*


Provides hygienic cleaning anytime anywhere

✓ REFRESHING WET WIPES
✓ SOFT ON SKIN
✓ HARSH ON BACTERIA

pH balanced

CLEANSE THOROUGHLY
7.3 x 6.1 in (185 mm x 155mm)


120 PCS

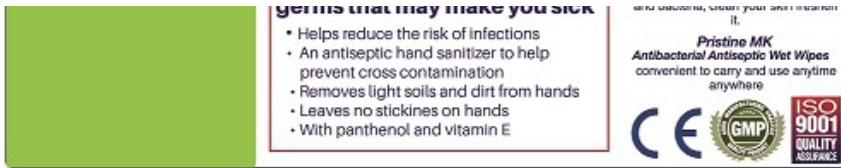


Antibacterial Antiseptic wet wipes
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NDC: 81214-600-01

ANTIBACTERIAL ANTISEPTIC WET WIPES

antibacterial antiseptic wet wipes cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81214-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	0.03 mL in 100 mL
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	0.01 mL in 100 mL
CETEARETH-12 (UNII: 7V4MR24V5P)	0.01 mL in 100 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.03 mL in 100 mL
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	0.01 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.03 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.03 mL in 100 mL
CYCLAMEN ALDEHYDE (UNII: 4U37UX0E1E)	0.01 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.1 mL in 100 mL
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	0.03 mL in 100 mL
WATER (UNII: 059QF0K00R)	99.52 mL in 100 mL
CETYL PALMITATE (UNII: 5ZA2S6B08X)	0.01 mL in 100 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.03 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81214-600-01	600 mL in 1 POUCH; Type 0: Not a Combination Product	11/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	11/01/2020	
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Labeler - PRISTINE MK LLC (117674251)

Registrant - FRESH CO COSMETICS SH.P.K (499428868)

Establishment			
Name	Address	ID/FEI	Business Operations
FRESH CO COSMETICS SH.P.K		499428868	manufacture(81214-600)

Revised: 12/2020

PRISTINE MK LLC