

ANTIBACTERIAL HAND WIPES- benzalkonium chloride cloth
AMERICAN EXCHANGE TIME 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.

78870-901 Antibacterial Hand Wipes 0.13% Benzalkonium Chloride

Active Ingredient

Benzalkonium Chloride 0.13 %

Purpose

Antimicrobial Agent

USE

Hand sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.

Warning

For external use only. Do not use:

- In children less than 2 months of age.
- On open skin wounds.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. 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. .

Directions

Apply to hands, allow to dry without wiping. .

Inactive ingredients

	<div><div>SafeAct</div><div>Personal Protective Supplies</div></div> <div><div>Caution: Please keep this product in a cool, dry place avoiding direct sunlight. Keep out of reach of children. If product gets into eyes, please rinse immediately with water. This product is insoluble in water. Avoid using in wounds or sensitive areas. Please place in the trash after use.</div></div>		<div><div><div>LIFT HERE</div><div>SafeAct</div><div>Antibacterial Hand Wipes</div><div>Kills 99% of Germs*</div><div>4 WIPES</div></div></div>		<div><div>"Kills 99% of germs in as little as 5 minutes"</div><div><div><div>Drug Facts</div><div><div>Active ingredient(s)</div><div>Purpose</div></div><div><div>Use(s)</div><div>Warnings</div></div><div><div>Directions</div><div>Other information(s)</div></div><div><div>Inactive ingredient(s)</div><div></div></div></div></div></div> <div><div>Questions or Comments?</div><div>Call 1-888-603-0028</div><div>www.ShopSafeAct.com</div><div>Dist. By American Exchange Time, LLC</div><div>1441 Broadway, 27th Floor</div><div>New York, NY 10018</div><div><div>To Dispense:</div><div>To Use:</div><div>To Reseal:</div><div>To Dispose:</div></div><div><div><div><div></div><div></div><div></div><div></div></div><div><div></div><div></div><div></div><div></div></div></div></div><div><div>NDC:</div><div>MADE IN CHINA</div><div>Manufactured: 06/2020</div><div>Expiration: 06/2022</div><div>Lot Number:</div></div></div>
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ANTIBACTERIAL HAND WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78870-901
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 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78870-901-01	80 in 1 BAG	06/23/2020	
1		420 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:78870-901-02	15 in 1 BAG	06/23/2020	
2		82 g in 1 POUCH; 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	06/22/2020	

Labeler - AMERICAN EXCHANGE TIME LLC (830332164)

Establishment			
Name	Address	ID/FEI	Business Operations
Kangna (Zhejiang) Medical Supplies Co., Ltd.		554530173	manufacture(78870-901)