COLEMERG ANTIBACTERIAL HAND SANITIZING WIPES- benzalkonium chloride cloth
Colemerg Products 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.

Colemerg Antibacterial Hand Sanitizing Wipes

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13 % w/v

Purpose

Antibacterial

Uses

- For sanitizing to decrease bacteria on the skin
- Recommended for repeated use

WARNINGS

For external use only

Do not use:

Over large areas of the body if you are allegic to any of the ingredients.

When using this product

do not get into eyes. 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.

Keep out of reach of children

If swallowed, get medical help or contact Poison Control Center right away (1-800-222-1222)

Directions

- Remove lid and open the seal.
- Pull up the corner of the center sheet, twist it and thread through the dispenser slipt in the lid.
- Pull sheet out at an angle. When finished close lid flap to retain moisure.

Other Information:

- Do not expose to direct sunlight, preferably place them in a cool place
- Do not use on furniture
- Do not flush down toilets, dispose in trash can

Inactive Ingredients:

Aqua/Water, Glycerin, Phenoxyethanol, Parfum/Fragrance, Polysorbate 20, Sodium PCA, Tetrasodium Edta, Ethylhexylglycerin, Citric Acid.

Package Labeling:

COLEMERG ANTIBACTERIAL HAND SANITIZING WIPES

benzalkonium chloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80171-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80171-002-00	20 in 1 BAG	09/20/2020	
1		3.2 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/20/2020	

Labeler - Colemerg Products LLC (117617946)

Revised: 11/2020 Colemerg Products LLC