ANTIBACTERIAL WIPES- benzalkonium chloride cloth Hangzhou Glamcos Biotech CO.,LTD

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.

Active Ingredient(s)

Benzalkonium Chloride 0.2%

Purpose

Antimicrobial

Use

Kills 99.99% of germs.

Warnings

For external use only. Keep out of eyes. In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if redness or irritation develops.

Keep out of sunlight.

Keep out of reach of children.

Directions

Peel back flap on front to pull out a towelette. Reseal the flap. No need ro rinse.

Inactive ingredients

Water Glycerin Propylene Glycol Polyaminopropyl Biguanide Phenoxyethanol Glodopropynyl Butylcarbamate Green Tea Extract.

100 Package Label - Principal Display Panel





80 Package Label - Principal Display Panel





40 Package Label - Principal Display Panel





20 Package Label - Principal Display Panel





ANTIBACTERIAL WIPES

benzalkonium chloride cloth

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76635-001
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Route of Administration TOPICAL

Active	Ingred	lie nt/ <i>E</i>	Active	Moiety
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Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients					
Ingredient Name	Strength				
POLYAMINO PRO PYL BIGUANIDE (UNII: DT9 D8 Z79 ET)					

GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76635-001-01	432 g in 1 BAG; Type 0: Not a Combination Product	05/01/2020			
2	NDC:76635-001-02	346 g in 1 BAG; Type 0: Not a Combination Product	05/01/2020			
3	NDC:76635-001-03	173 g in 1 BAG; Type 0: Not a Combination Product	05/01/2020			
4	NDC:76635-001-04	87 g in 1 BAG; Type 0: Not a Combination Product	05/01/2020			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/01/2020				

Labeler - Hangzhou Glamcos Biotech CO.,LTD (554476017)

Registrant - Hangzhou Glamcos Biotech CO.,LTD (554476017)

Establishment						
Name	Address	ID/FEI	Business Operations			
Hangzhou Glamcos Biotech CO.,LTD		554476017	manufacture(76635-001)			

Revised: 4/2020 Hangzhou Glamcos Biotech CO.,LTD