FASTRAY INTL ANTIBACTERIAL WET WIPES- benzalkonium chloride solution NINGBO SHINEFLY COMMODITY 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.

The ANTIBACTERIAL WET WIPE is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations.

- a. The ANTIBACTERIAL WET WIPE is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations
- b. Phenoxyethanol 0.5 %
- c. Ethylhexylglycerin 0.1 %
- d. Didecyldimonium Chloride 0.2 %
- e. Propylene Glycol 0.1 %
- f. Glycerin 0.1 %
- g.Fragrance 0.1 %
- h. Alcohol Denat 10.0 %
- i. water 88.77 %

Active Ingredient(s)

Benzalkonium Chloride 0.13%. Purpose: Antimicrobial Agent

ANTIBACTERIAL: ANTIBACTERIAL WET WIPE

USE

ANTIBACTERIAL WET WIPE to decrease bacteria on skin

warnings

For external use only.

Do Not Use

if you are allergic 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 irrigation or rash develops and continues for more than 72 hours

keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center reght away.

Directions

- adults and children 2 years and over, under 2 years ask doctor before use.
- apply to hands
- allow to dry without wiping

other information

Wet Hand Wipes kill 99.9% of germs and wipe away dirt. Providing a better clean than hand sanitizers. They are specially formulated to be tough on dirt and germs. yet gentle on skin. so you can confidently keep your hands clean when soap and water are not available.

inactive ingredients

purified water, Phenoxyethanol, Ethylhexylglycerin, Didecyldimonium Chloride, Propylene Glycol, Glycerin, Fragrance, Alcohol Denat

Package Label, Principal Display Panel

xP NDC:



FASTRAY INTL ANTIBACTERIAL WET WIPES

benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75441-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.00585 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)	0.1 g		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.001 g		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.001 g		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.001 g		
WATER (UNII: 059QF0KO0R)	0.8877 g		
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.005 g		
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	0.002 g		
GLYCERIN (UNII: PDC6A3C0OX)	0.001 g		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75441-001-12	1 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
2	NDC:75441-001-19	15 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
3	NDC:75441-001-18	20 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
4	NDC:75441-001-17	30 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
5	NDC:75441-001-16	60 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
6	NDC:75441-001-15	80 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
7	NDC:75441-001-14	100 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		
8	NDC:75441-001-13	120 in 1 BAG; Type 0: Not a Combination Product	04/20/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/20/2020		

Labeler - NINGBO SHINEFLY COMMODITY CO.,LTD. (554530228)

Revised: 4/2020 NINGBO SHINEFLY COMMODITY CO.,LTD.