ZIVA PERFUMED WIPES BAKHOOR- benzethonium chloride cloth Ziva Wetwipes FZCo

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.

Drug Facts

Active Ingredient:

Benzethonium Chloride 0.1%

Direction for use:

Peel back the front label slowly. Pull wipes as needed. Reseal pouch by firmly running thumb over label to prevent moisture loss.

Precautions:

For external use only. Do not apply to irritated or damaged skin. In case of gluteal erythema (redness of skin), contact your doctor or pharmacist. Keep in a cool place away from direct sun light. Prevent contact with eyes. In case of irritation wash away with water immediately.

Store below 25°C | For external use only | Keep out of reach of children

Ingredients:

Aqua, Pentylene Glycol and Glyceryl Caprylate / Caprate, Perfume, PEG 40 Hydrogenated Castor Oil, Aloe Barbadensis Leaf Juice, Citric Acid, Disodium EDTA.

Product label



ZIVA PERFUMED WIPES BAKHOOR

benzethonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81450-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)			
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
SANTALUM ALBUM SEED OIL (UNII: J8A90C3A98)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:81450- 003-01	10 in 1 PACKAGE	12/24/2021	
1	3.42 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not inal	part333A	12/24/2021	
	part333A	12/24/2021	

Labeler - Ziva Wetwipes FZCo (559186188)

Registrant - Dirra USA (117678868)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ziva Wetwipes FZCO		559186188	manufacture(81450-003)	

Revised: 12/2021 Ziva Wetwipes FZCo