

SHIERJIE DISINFECTING SOFT WIPES ANTIBACTERIAL- shierjie disinfecting soft wip es antibacterial cloth

Shenzhen Shierjie Biological Engineering 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.

43116-004

SHIERJIE DISINFECTING SOFT WIPES Antibacterial

Active Ingredient

Benzalkonium Chloride 0.09%

Dodecyl Dimethyl Ammonium Chloride 0.04 %

Purpose

Antimicrobial

Decreases bacteria on skin

Warnings

For external use only.Keep away from heat or flame.

If you are allergic to any of the ingredients.If children less than 2 months of age.

When using this produc, do not get into eyes.If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if iri tation or rash develops and continues for more than 72 hours.

If swallowed,get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years and over

Apply to hands

Allow to dry without wiping

Children under 2 years

Ask a doctor before use

Other information

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Inactive ingredients

Aloe Barbadensis Extract , Glycerin , Aqua , Non-woven

Package Label - Principal Display Panel

43116-004-02



Drug Facts		Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away.
Active ingredient	Purpose	
Benzalkonium Chloride 0.09%.....	Antiseptic	Directions
Dodecyl Dimethyl Ammonium Chloride 0.04%.....	Antiseptic	
USE Decreases bacteria on skin	Adults and children 2 years and over	<ul style="list-style-type: none"> ■ Apply to hands ■ Allow to dry without wiping
Warning: For external use only. Keep away from heat or flame.	Children under 2 years	Ask a doctor before use
Do not use: If you are allergic to any of the ingredients. If children less than 2 months of age.	Inactive ingredients	
WHEN USING SECTION: When using this product, do not get into eyes. If contact occurs, rinse thoroughly with water.	Aloe Barbadosensis Extract, Glycerin, Aqua, Non-Woven	
OTC STOP USE SECTION: Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.		

SHIERJIE DISINFECTING SOFT WIPES ANTIBACTERIAL

shierjie disinfecting soft wipes antibacterial cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43116-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.09 g in 100
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.04 g in 100

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43116-004-02	10 in 1 BAG; Type 0: Not a Combination Product	12/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	12/21/2020	
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Labeler - Shenzhen Shierjie Biological Engineering Co., LTD (547610261)

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen Shierjie Biological Engineering Co., LTD		547610261	manufacture(43116-004)

Revised: 12/2020

Shenzhen Shierjie Biological Engineering Co., LTD