SANITARY WET WIPES- sanitary wet wipes cloth Dandong Xinshidai Biotec Pharmaceuticals 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.

SANITARY WET WIPES

Active ingredient

Benzalkonium chloride 0.13% w/w

Purpose

Antiseptic

Uses

Suitable for wiping hands, face, skin and other unbroken skin.

Warnings

For external use only.

When using this product avoid to contact eyes, wounds and other sensitive parts. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

This product is insoluble in water, please put it in the trash after use.

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Directions

Take out the wet wipes and use directly

Other Information

- · Store in a cool place, avoid sunlight or high temperature.
- · Shelf Life: 2 years
- · Product specification: 160mm × 200mm
- · Product features: pure cotton texture, soft and comfortable

It has bactericidal effect on Staphylococcus aureus, Escherichia coli and Candida albicans.

· See the code on the package for the expiration date and production lot number

Inactive Ingredients

RO water, Bronopol

Net Contents: 1 PCS; NDC: 81306-001-01

babiinaa





NDC: 81306-001-01

Net Contents: 1 PCS

Drug Facts

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Inactive Ingredients

RO water, Bronopol

Manufacturer

Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD

Manufacturing Address: Langtoushuntian, Zhenxing District, Dandong City, Liaoning Province, CHINA Company Address: No.35 Jihuan Road, Zhenxing District, Dandong City, Liaoning Province, 118009,

CHINA

Tel: 86-415-6152128 Fax: 86-415-6151318

Net Contents: 10PCS; NDC: 81306-001-02







NDC: 81306-001-02

Net Contents: 10PCS

Drug Facts

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 $\bullet \, \mathsf{See} \, \mathsf{the} \, \mathsf{code} \, \mathsf{on} \, \mathsf{the} \, \mathsf{package} \, \mathsf{for} \, \mathsf{the} \, \mathsf{expiration} \, \mathsf{date} \, \mathsf{and} \, \mathsf{production} \, \mathsf{lot} \, \mathsf{number}$

Inactive Ingredients

RO water, Bronopol

Manufacturer

Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD

Manufacturing Address: Langtoushuntian, Zhenxing District, Dandong City, Liaoning Province, CHINA Company Address: No.35 Jihuan Road, Zhenxing District, Dandong City, Liaoning Province, 118009, CHINA

Tel: 86-415-6152128 Fax: 86-415-6151318

Net Contents: 60PCS; NDC: 81306-001-03







Net Contents: 60PCS

Drug Facts

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Tel: 86-415-6152128 Fax: 86-415-6151318

Net Contents: 72PCS; NDC: 81306-001-04







NDC: 81306-001-04

Net Contents: 72PCS

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Tel: 86-415-6152128 Fax: 86-415-6151318

Net Contents: 80PCS; NDC: 81306-001-05





80PCS



NDC: 81306-001-05

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Manufacturer

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Tel: 86-415-6152128 Fax: 86-415-6151318

Net Contents: 100PCS; NDC: 81306-001-06







Net Contents: 100PCS

Drug Facts

Active ingredient

Purpose

Benzalkonium chloride 0.13%w/w......Antiseptic

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SANITARY WET WIPES

sanitary wet wipes cloth

D		TC	. •
Prod	liict	Intor	mation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81306-001
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TOPICAL Route of Administration

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
BRONOPOL (UNII: 6PU1E16C9W)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81306-001-01	1 in 1 BAG	11/06/2020		
1		5.5 g in 1 PATCH; Type 0: Not a Combination Product			
2	NDC:81306-001-02	10 in 1 BAG	11/06/2020		
2		5.5 g in 1 PATCH; Type 0: Not a Combination Product			
3	NDC:81306-001-03	60 in 1 BAG	11/06/2020		
3		5.5 g in 1 PATCH; Type 0: Not a Combination Product			
4	NDC:81306-001-04	72 in 1 BAG	11/06/2020		
4		5.5 g in 1 PATCH; Type 0: Not a Combination Product			
5	NDC:81306-001-05	80 in 1 BAG	11/06/2020		
5		5.5 g in 1 PATCH; Type 0: Not a Combination Product			
6	NDC:81306-001-06	100 in 1 BAG	11/06/2020		
6		5.5 g in 1 PATCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/06/2020	

Labeler - Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD (527128186)

Registrant - Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD (527128186)

Establishment			
Name	Address	ID/FEI	Business Operations
Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD		527128186	manufacture(81306-001), label(81306-001), pack(81306-001)

Revised: 12/2020 Dandong Xinshidai Biotec Pharmaceuticals Co.,LTD