

DISINFECTING WET WIPE- polyhexamethylene biguanide cloth
Five Hertz (Xiamen) Medical Supplies Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Disinfecting Wet Wipe

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Active Ingredient(s)

Polyhexamethylene Biguanide 0.9mg/cloth. Purpose: Antiseptic

Purpose

Antiseptic, Disinfecting Wet Wipe

Use

Disinfecting Wet Wipe to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. 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.

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Directions

- Take out the wet wipes and wipe directly. Disinfecting time on hand no more than 1 min; Disinfecting time on whole skin and mucosa no more than 5 min; Disinfecting time on ordinary object surface no more than 5 min.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP

Package Label - Principal Display Panel



Japanese medical polymer material research crystallization

[The period of validity] Two Years
 [Manufacturer] Five Hertz(Xiamen) Medical Supplies Co.LTD
 [Executive Standard] WS 575-2017
 [Hygienic License] (Min) WeiGaoZi (2018) No. (02)0004
 [Address] B9 Building 2/F, Xiamen Biomedical Industrial Park, No.2064 West Wengjiao Road, Haicang District, Xiamen
 [Postal Code] 361027
 [Web Site] www.5hz-medical.com
 [Tel] 0592-5882100

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Please take good care of the environment.
 production lot number and production date
 Printed on the packaging

Disinfecting Wipe

Japanese medical polymer material research crystallization

Disinfecting Wipe

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Disinfecting Wipe

Free from Alcohol and Fragrance

PHMB
Polyhexamethylene Biguanide

>99%
Average Disinfecting Rate

Free from Alcohol and Fragrance

Japan Tech + Material

Disinfecting Wipe

Japanese medical polymer material research crystallization

Comfort to China's latest Health industry standards WS 575-2017

Derma Sensitivity test
 No Response
 Vaginal mucosa irritation test
 No Irritation

The product's safety and Disinfecting rate have been tested by the national key laboratory of health treatment safety and applicability of China

[Product Name] Disinfecting Wipe
 [Main Ingredient] Super Soft Spunlace Non-woven Fabric, Polyhexamethylene Biguanide, RO Purified Water
 [Active Ingredient Content] Polyhexamethylene Biguanide 0.015%-0.025%
 [Application Scope] Suitable for hand, skin, mucosa (including vaginal mucosa) and common object surface cleaning disinfection. It could be used for infants.
 [Usage Method] Take out the wet wipes and wipe directly. Disinfecting time on hand < 1 min; Disinfecting time on whole skin and mucosa < 5 min; Disinfecting time on ordinary object surface < 5 min.
 [Matters Need Attention] ① Allergic to use disinfecting wipes on hand, skin and mucosa, should be used with caution;
 ② If you feel sensitive or uncomfortable, please stop using of wipe with clean water;
 ③ Must not be used for the prevention of sexually transmitted diseases;
 ④ Each disinfecting wet wipe is limited to one-time use and cannot be reused;
 ⑤ Please keep the product in a cool and dry place, away from direct sunlight.

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DISINFECTING WET WIPE

polyhexamethylene biguanide cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76579-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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POLIHEXANIDE (UNII: 322U039GMF) (POLIHEXANIDE - UNII:322U039GMF)		POLIHEXANIDE	0.9 mg	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76579-301-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76579-301-02	50 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76579-301-03	80 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76579-301-04	120 in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/30/2020		

Labeler - Five Hertz (Xiamen) Medical Supplies Co., Ltd. (553972905)

Establishment

Name	Address	ID/FEI	Business Operations
Five Hertz (Xiamen) Medical Supplies Co., Ltd.		553972905	manufacture(76579-301)

Revised: 4/2020

Five Hertz (Xiamen) Medical Supplies Co., Ltd.