

ANTIBACTERIAL WIPES- benzalkonium chloride cloth

Zhejiang Yiwu Anrou Sanitation Article 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.

Anrou-PGM, Antibacterial wipes, Benzalkonium Chloride (rev)

ACTIVE INGREDIENT

Benzalkonium Chloride, 0.11875% w/v Purpose: Antibacterial

Purpose

Antibacterial

WARNINGS

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Do not use

On children less than 2 years of age, or on open skin wounds.

STOP USING AND ASK 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 Poison Control Center right away.

Use

Sanitizing Wipe helps to reduce bacteria & virus that can potentially cause disease.

For use when soap & water are not available.

DIRECTIONS

Store in a cool and dry place.

Remove cover.

Pull up wipe corner from center of roll.

Thread through hole in the cover.

Replace cover.

Open center cap on cover to remove wipe.

When not using, close center cap securely to prevent moisture loss.

Reseal and let hands dry.

No need to rinse.

CAUTION

WARNING FLAMMABLE

Keep away from heat, spark, electrical, fire or flame.

Store in a cool and dry place.

INACTIVE INGREDIENT

1,2-Propanediol, Cereals Extraction Extract, 2-Phenoxyethanol, 2-Methy-4-isothiazolin-3-one, Iodopropynyl Butylcarbamate, Water

Package label. Principal display panel

30X11.5CM



ANTIBACTERIAL WIPES			
benzalkonium chloride cloth			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78356-216
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	5 mg

Inactive Ingredients				
Ingredient Name			Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			0.0945 mg	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			0.2625 mg	
BARLEY (UNII: 5PWM7YLI7R)			2.1 mg	
PHENOXYETHANOL (UNII: HIE492ZZ3T)			0.84 mg	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78356-216-21	80 in 1 PAIL; Type 0: Not a Combination Product	09/05/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	09/05/2020	

Labeler - Zhejiang Yiwu Anrou Sanitation Article Co., Ltd (547950139)

Registrant - A03 Lab of BTS (548009541)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Yiwu Anrou Sanitation Article Co., Ltd		547950139	manufacture(78356-216) , label(78356-216)

Revised: 9/2020

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