ALLWIPES- benzalkonium chloride cloth JAINAM INVAMED PRIVATE LIMITED

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.

ALLWIPES® BKC WIPES

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Uses:

As a Sanitizer to Help Reduce Bacteria on the Skin.

Warnings

For external use only.

Flammable: Keep away from fire or flame.

Do Not Use

• In Children in less than 2 months of age. • On Open skin Wound.

When using this product avoid contact with eyes and mouth. If in eyes, flush thoroughly with water.

Discontinue use and contact a doctor if irritation and redness develop and conditions persist for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Directions:

• Tear the shrink wrap. • Rotated the lid of the canister toward anti-clock wise direction. • Pull the foil seal. • Pull wipes from center of the roll and thread through "+" on the underside of the lid. • Pull wipe from canister at 90° angle. • Close lid.

Inactive Ingredients

Water.

Other Information:

• Store at room temperature 15°-30°C (59°-86°F).

HAND AND BODY SANITIZING WIPES

KILLS 99.99% OF GERMS

EFFECTIVE & QUICK DRYING

Mild, non-irritating and safe for skin. Reduces the fear of infection. Use for hands and surfaces, that are used by multiple people: Mobile cell phones, Handles, Switches, Door bell buttons, Elevator buttons, Public transport, Common Laptops, equipment, Public Waiting areas etc. These wipes can be used to disinfect electronic equipment like handheld gadgets.

Manufactured by:

jainam invamed Private Limited

111,112, Shubh Ind Est,

Nr Chinchpada Bus Stop,

Waliv Rd, Vasai(E)-401208,

Mumbai, Maharashtra, India.

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Customer care No.: +91 9819446969

ISO 9001.2015 13485:2016

Packaging



ALLWIPES

benzalkonium chloride cloth

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:81297-101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Str	ength Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO UNII:7N6 JUD5X6 Y)	DNIUM - BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81297-101-01	1 in 1 PACKET	12/21/2020	
1		2 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:81297-101-02	25 in 1 CANISTER	12/21/2020	
2		3 mL in 1 PACKAGE; Type 0: Not a Combination Product		
3	NDC:81297-101-03	60 in 1 CANISTER	12/21/2020	
3		3 mL in 1 PACKAGE; 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	12/21/2020	

$\pmb{Labeler} \textbf{ - } \texttt{JAINAM} \texttt{ INVAMED PRIVATE LIMITED (854117783)}$

Establishment

Littonisment					
	Name	Address	ID/FEI	Business Operations	
	JAINAM INVAMED PRIVATE LIMITED		854117783	manufacture (8 129 7-10 1)	

Revised: 12/2020 JAINAM INVAMED PRIVATE LIMITED