

ANTISEPTIC TOWELETTES- benzalkonium chloride cloth
Custom Kits Company Inc

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.

Antiseptic Towelette

Drug Facts

Active Ingredients

Benzalkonium chloride .4%

Purpose Section

Antiseptic

Uses

Antiseptic to help prevent the risk of infection

Warning

For External Use Only

Do Not

use in the eyes

use as a first aid antiseptic longer than 1 week

apply over large areas of the body

Stop Use

if the condition persists or gets worse

Ask a doctor in case of

deep or puncture wounds, animal bites, or serious burns

Keep out of reach of children section

If swallowed, get medical help or contact a poison control center right away.

Directions

Clean the affected area

apply a small amount of the product on the area

may be covered with a sterile bandage

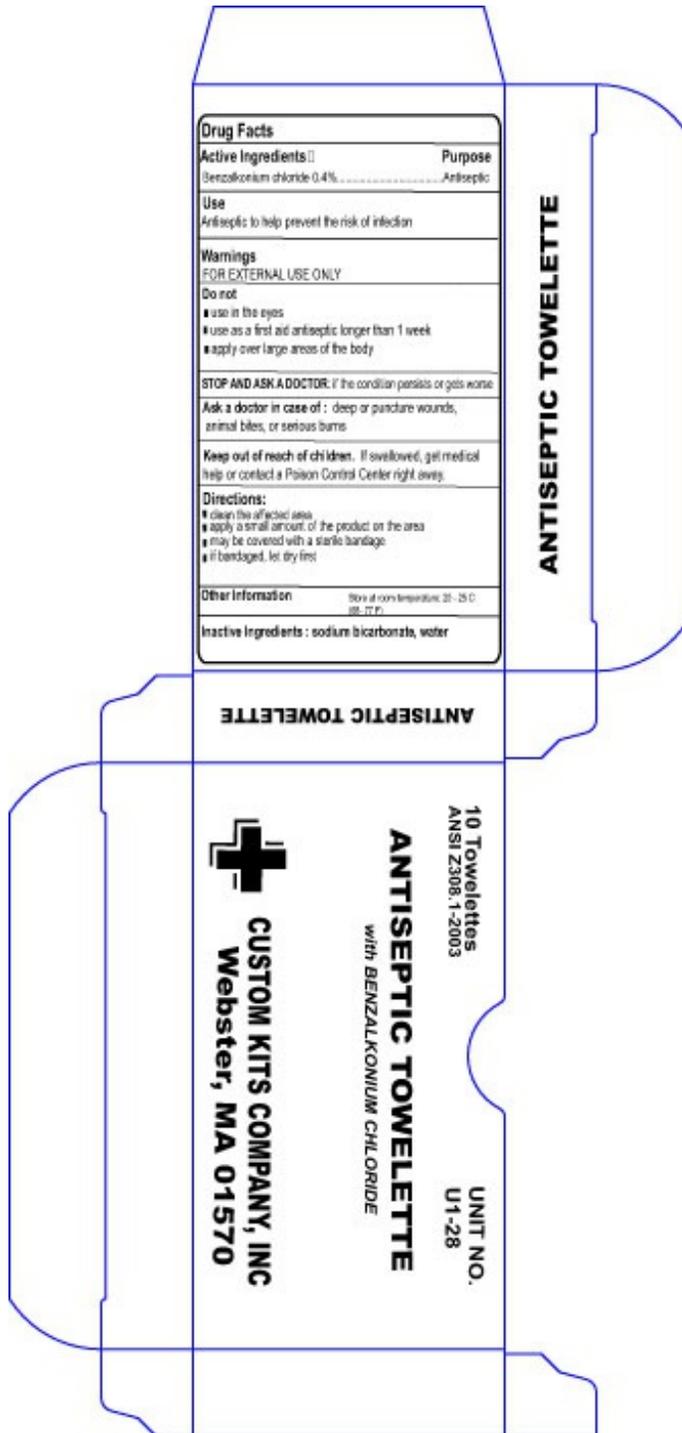
if bandaged let dry first

Other information

store at room temperature 20-25C (68-77 F)

Inactive Ingredients

Sodium bicarbonate, water



ANTISEPTIC TOWELETTES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 183-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68 183-120-01	10 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	10/22/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/22/2015	

Labeler - Custom Kits Company Inc (928643712)**Establishment**

Name	Address	ID/FEI	Business Operations
Dynarex Corporation		008124539	manufacture(68 183-120)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Kits Company Inc		928643712	repack(68 183-120) , relabel(68 183-120)

Revised: 12/2017

Custom Kits Company Inc