

ANTISEPTIC WIPES- benzalkonium chloride (0.13%) cloth

Flex Beauty Labs

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.

Germout- Wet Wipes Antibacterial

Active ingredients

Benalkonium chloride (0.13%)

Purpose

Antibacterial

Use

Use to reduce bacteria on the skin

Warnings

For external use only

Do Not Use

Do not use if you are allergic to any of the ingredients.

When using this product

When using this product do not use in or near eyes.

In cases of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

Stop use and ask a doctor if irritation or redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions:

- Adults and children over 2 years of age: Apply to hands. Allow to dry without rinsing.
- Children under 2 years of age: ask doctor prior to use

Inactive ingredients

water, glycerin, sodium PCA, Aloe barbadensis leaf juice, fragrance, polysorbate 20, tetrasodium EDTA, phenoxyethanol, ethylhexylglycerin, citric acid

principal display panel

60 WIPES

14 X 19 cm

5.5 IN X 7.4 IN



20 WIPES

14 X 19 cm

5.5 IN X 7.4 IN



ANTISEPTIC WIPES

benzalkonium chloride (0.13%) cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72308-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72308-015-20	20 in 1 PACKAGE	06/23/2020	
1		1 mg in 1 PACKET; Type 1: Convenience Kit of Co-Package		
2	NDC:72308-015-60	60 in 1 PACKAGE	06/23/2020	
2		1 mg in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/23/2020	

Labeler - Flex Beauty Labs (080858917)

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