

ASSURED- benzalkonium chloride swab
HIGIENE + SALUD, S.A. DE C.V.

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.

Benzalkonium Chloride 0.125%

Antibacterial

For external use only

Over large areas of the body if you are allergic to any of the ingredients.

Do not get into eyes.

If contact occurs, rinse thoroughly with water.

If irritation or rash develops and continues for more than 72 hours.

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

- Thoroughly wipe hands and face as desired.
- allow to dry without wiping.
- Discard wipe in trash receptacle after use. Do not flush.

Store at room temperature. Cold weather may cloud this product. It's antiseptic properties are not affected.

Water, Propylene Glycol, Polysorbate 20, Sodium Cocoamphoacetate, Fragrance, Methylchloroisothiazolinone/ Methylisothiazolinone, Aloe Extract, Tetrasodium EDTA, Citric Acid, Vitamin E.

Dosage: Swab - Administration: Topical

- **Convenient**

Easy to use & carry anywhere!

- **Clean-up**

Use to wash up quickly when soap and water are not available.

- **Moisturize**

Contains soothing Aloe to help moisturize your skin and leave it feeling soft and smooth.

Drug Facts	Active ingredient Benzalkonium Chloride 0.125%.....	Purpose Antibacterial
Use For hand washing to decrease bacteria on the skin. May be used on face, arms and legs.		
Warnings For external use only Do not use over large areas of the body if you are allergic to any of the ingredients. When using this product do not get into eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		
Directions • Thoroughly wipe hands and face as desired. • Allow to dry without wiping. • Discard wipe in trash receptacle after use. Do not flush.		
Other information Store at room temperature. Cold weather may cloud this product. Its antiseptic properties are not affected.		
Inactive ingredients Water, Propylene Glycol, Polysorbate 20, Sodium Cocamphacetate, Fragrance, Methylchloroisothiazolinone / Methylisothiazolinone, Aloe Extract, Tetrasodium EDTA, Citric Acid, Vitamin E.		

ASSURED

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52629-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.125 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	98.54 mg in 100 mg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mg in 100 mg
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.3 mg in 100 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.01 mg in 100 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 mg in 100 mg
SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	0.2 mg in 100 mg
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	0.1 mg in 100 mg
EDETATE SODIUM (UNII: MP1J8420LU)	0.03 mg in 100 mg
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.018 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52629-800-03	16 in 1 BOX	12/20/2018	
1		1 in 1 PACKAGE		

1	0.3 mg in 1 POUCH; 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	part333E	12/20/2018	

Labeler - HIGIENE + SALUD, S.A. DE C.V. (814608832)

Registrant - HIGIENE + SALUD, S.A. DE C.V. (814608832)

Establishment

Name	Address	ID/FEI	Business Operations
HIGIENE + SALUD, S.A. DE C.V.		814608832	manufacture(52629-800) , pack(52629-800) , label(52629-800)

Revised: 1/2022

HIGIENE + SALUD, S.A. DE C.V.