

HAND WIPES- benzalkonium chloride swab
Advanced Ultrasound Solutions 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.

Drug Facts

Active ingredient

Benzalkonium chloride.....0.13%

Purpose

Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

␣Do not use if you are allergic to any of these ingredients

When using this product

Avoid contact with eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor

If irritation or redness develops, or if condition persists 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

- adults and childrens 2 years and over: apply to hands, allow to dry without wiping
- children under 2 years: ask a doctor before use

To Dispense: ␣Peel back front label slowly. Remove Wipes

To Reseal: ␣Firmly rub thumb over label. Dispose of wipe in trash. Do not flush

Other information

- Store below 95°F (35°C)
- keep closed tightly
- may discolor certain fabrics or surfaces

Inactive ingredients

Purified Water, Phenoxyethanol, Decyl Glucoside, Potassium Sorbate, Sodium Benzoate, Disodium EDTA, Citric Acid, Aloe Barbadensis (Aloe) Leaf Extract, Tocopheryl Acetate, Organic Citrus Aurantium Bergamia Fruit Oil.

Principal Display Panel

NDC: 77677-013-20

SONO® HEALTHCARE

MADE IN USA

HAND SANITIZING WIPES

WITH MOISTURIZER AND BERGAMOT ESSENTIAL OIL

Kills 99.9% of most common germs

20 Wipes

New Contents: 20 pre-moistened sanitizing wipes, 7X8



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BERGAMOT ESSENTIAL OIL



Kills 99.99% of most common germs

HAND WIPES

benzalkonium chloride swab

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77677-013	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.13 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77677-013-20	20 in 1 PACKAGE	05/15/2020	
1		0.13 g in 1 PACKET; 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	05/15/2020	

Labeler - Advanced Ultrasound Solutions Inc. (079552984)

Revised: 5/2020

Advanced Ultrasound Solutions Inc.