SANITIZING ALCOHOL FREE WIPES- sanitizing alcohol free wipes cloth
Shedrain Corporation

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.

Active Ingredient

Active ingredient for this sanitizing alcohol-free wipes is Benzalkonium chloride

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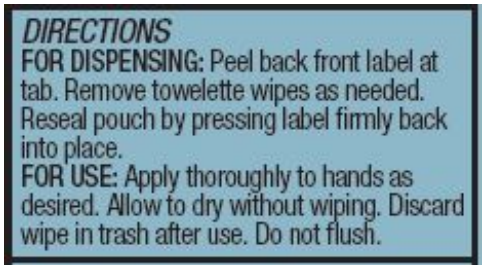
Purpose

Hand Sanitizer to help decrease bacteria on the skin.

Use

For dispensing: Peel back front label at tab. Remove towelette wipes as needed. Reseal pouch by pressing label firmly back into place.

For use: Apply thoroughly to hands as desired. Allow to dry without wiping. Discard wipe in trash after use. Do not flush.

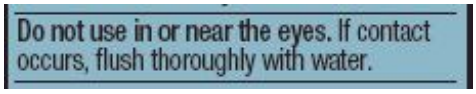


Warnings

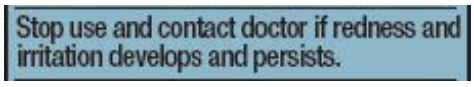
For external use only.

Do not use

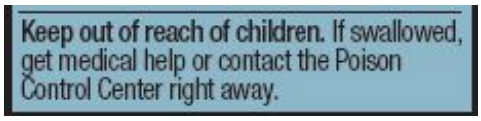
Do not use in or near the eyes. If contact occurs, flush thoroughly with water.



Stop use and contact doctor if redness and irritation develops and persists.

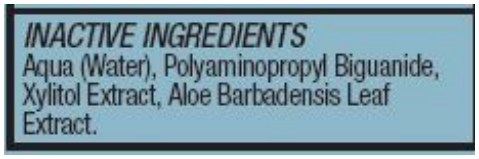


Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Inactive ingredients

Aqua (Water), Polyaminopropyl Biguanide, Xylitol Extract, Aloe Barbadensis Leaf Extract.



Dosage

FOR DISPENSING: Peel back front label at tab. Remove towelette wipes as needed.

FOR USE: Apply thoroughly to hands asdesired. Allow to dry without wiping.

Package Label - Principal Display Panel

20-pack. NDC: 80380-100-01

SANITIZING ALCOHOL FREE WIPES

sanitizing alcohol free wipes cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80380-100
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 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	0.5 mg in 100 mg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.04 mg in 100 mg
WATER (UNII: 059QF0KO0R)	99.3 mg in 100 mg
XYLITOL (UNII: VCQ006KQ1E)	0.03 mg in 100 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80380-100-01	20 mg in 1 PACKET; Type 0: Not a Combination Product	10/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/23/2020	

Labeler - Shedrain Corporation (009025552)

Establishment

Name	Address	ID/FEI	Business Operations
Zhangzhou Zhongnan Nursing Products Co., Ltd		416376835	manufacture(80380-100)

Revised: 10/2020 Shedrain Corporation