CLORALEN TM ANTIBACTERIAL WIPES- benzalkonium chloride liquid
INDELPA, 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.

Antibacterial

BENZALKONIUM, CHLORIDE 0.125%

Hand sanitizer to help reduce bacteria on the skin

For external use only.

If you are allergic to any of the ingredients

Do not get into eyes.

If contact occurs, rinse throughly 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

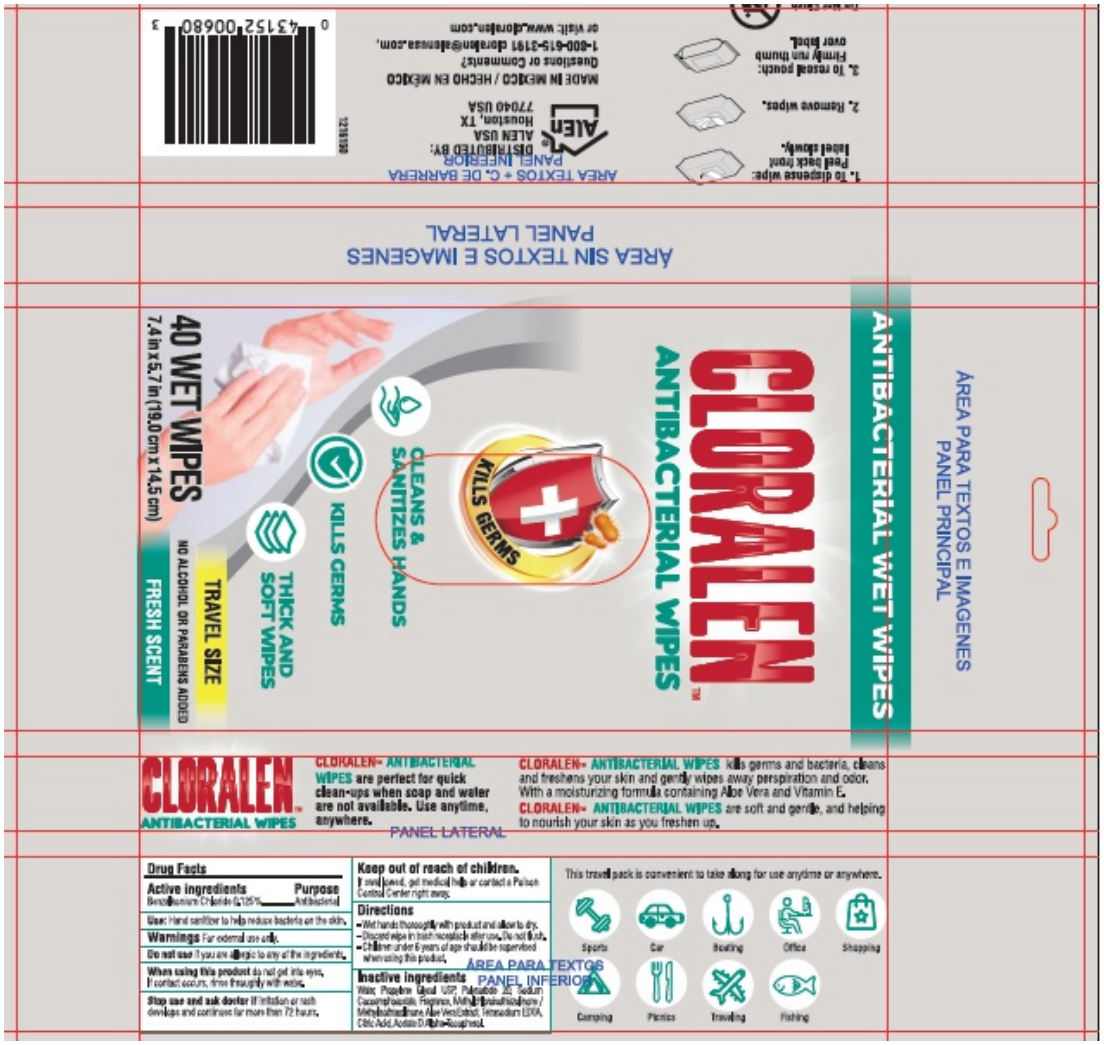
- wet hands throughly with product and allow to dry.

-discard wipe in trash receptacle after use. Do not flush

- chuldren under 6 years af age should be supervised whe using this product

water, propylene glycol USP, polysorbate 20, sodium cocoamphoacetate, fragrance, methylchloroisothiazolinone / methylisothiazolinone, aloe vera extract, tetrasodium EDTA, citric acid, acetate D alpha- tocopherol

Topical admistration



CLORALEN TM ANTIBACTERIAL WIPES

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70697-802
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
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 mg in 100 mg
EDETATE SODIUM (UNII: MP1J8420LU)	0.03 mg in 100 mg
WATER (UNII: 059QF0KO0R)	98.567 mg in 100 mg
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII:	0.1 mg in 100 mg

15O9QS218W)	0.1 mg in 100 mg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mg in 100 mg
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.018 mg in 100 mg
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.1 mg in 100 mg
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.3 mg in 100 mg
SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	0.2 mg in 100 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.05 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70697-802-01	24 in 1 CASE	09/01/2020	
1		0.375 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	09/01/2020	

Labeler - INDELPA, S.A DE C.V (811072487)

Registrant - INDELPA, S.A DE C.V (811072487)

Establishment

Name	Address	ID/FEI	Business Operations
INDELPA, S.A DE C.V		811072487	pack(70697-802) , manufacture(70697-802) , label(70697-802) , analysis(70697-802)

Revised: 1/2022 INDELPA, S.A DE C.V