

WIPES- benzalkonium chloride cloth
Skaffles Group Limited Liability Company

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.

77720-007 WIPES 0.3% BENZALKONIUM CHLORIDE

Active Ingredient

Benzalkonium Chloride 0.3%

Purpose

Antibacterial

USE

Use for hand sanitizing to decrease bacteria on the skin recommended for repeated use.

Warning

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

Keep out of reach of children.

Directions

Directions • Adults and children 2 yrs and over, apply to hands and allow skin to dry without wiping.

• Children under 2, ask doctor before use.

Inactive ingredients

Water, Phenoxyethanol, Sodium benzoate, Propylene glycol, Aloe barbadensis leaf juice, PEG-8 dimethicone, Disodium edta, Citric acid.

Drug Facts

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WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77720-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

PEG-8 DIMETHICONE (UNII: GIA7T764OD)

DISODIUM EDTA-COPPER (UNII: 6V475AX06U)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

SODIUM BENZOATE (UNII: OJ245FE5EU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77720-007-01	1 in 1 BAG	07/20/2020	
1		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:77720-007-02	15 in 1 POUCH	07/20/2020	
2		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:77720-007-03	20 in 1 POUCH	07/20/2020	
3		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:77720-007-04	25 in 1 POUCH	07/20/2020	
4		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:77720-007-05	30 in 1 POUCH	07/20/2020	
5		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:77720-007-06	50 in 1 POUCH	07/20/2020	
6		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:77720-007-07	75 in 1 POUCH	07/20/2020	
7		2.7 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:77720-007-08	100 in 1 POUCH	07/20/2020	
8		2.7 g in 1 NOT APPLICABLE; 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	07/20/2020	

Labeler - Skaffles Group Limited Liability Company (831115642)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 7/2020

Skaffles Group Limited Liability Company