WET WIPES- wet wipes cloth QUANZHOU V-CARE SANITARY PRODUCTS CO.,LTD

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.

80515-003 Wet wipes

Active Ingredient(s)

Benzalkonium chloride (0.13%)

Purpose

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Use

Instruction for use

Warnings

When using this product

Caution: Please put it in a cootapd dry place, avoid direct sunlight, do not let children touch it

Do not use

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Directions

Gently open the protective seal

Remove the wipes from the package and use it directly on the skin Use the wipe to clean and avoid to use on sensitive areas, such as eyes and wounds Once you have finished, close the package by pressing the protactive seal Avoid to keep the protective seal uncovered

Other information

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Inactive ingredients

Aqua (75%) Glycerin(0.5%)















WET WIPES

wet wipes cloth

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Product	Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80515-003
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100

Inactive Ingredients

inactive ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80515-003-01	10 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80515-003-02	20 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80515-003-03	40 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80515-003-04	50 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:80515-003-05	60 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
6	NDC:80515-003-06	80 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:80515-003-07	100 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - QUANZHOU V-CARE SANIT ARY PRODUCT S CO.,LTD (543052297)

Establishment					
Name	Address	ID/FEI	Business Operations		
QUANZHOU V-CARE SANITARY PRODUCTS CO.,LTD		543052297	manufacture(80515-003)		

Revised: 9/2020