REEARTH HAND SANITIZER WIPE- benzalkonium chloride cloth
NuGenTec

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.

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re:earth wipe Hand Sanitizer

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antiseptic, Hand Sanitizer, Antibacterial

Use

Hand Sanitizer wipe to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Wet hands thoroughly with the product to cover all surfaces. Allow to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 0-40C (32-104F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

160 in Canister NDC: 77368-011-20

REEARTH HAND SANITIZER WIPE

benzalkonium chloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77368-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	6.8 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-011-10	100 in 1 CANISTER	10/13/2020	
1		475 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:77368-011-16	160 in 1 CANISTER	10/13/2020	
2		560 mL in 1 PACKAGE; 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	03/30/2020	

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-011)

Revised: 10/2020 NuGenTec