

CLISEN- sanitizer spray spray

Clisen

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.

Clisen-AIO Sanitizer Spray

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer spray 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

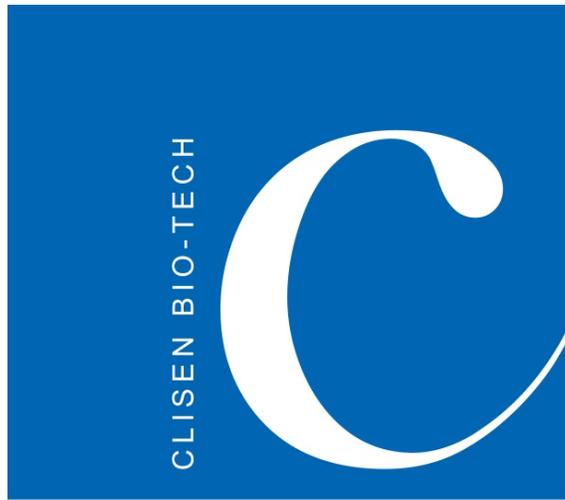
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, glycerin, benzalkonium chloride, dmdm hydantoin, alpha tocopherol, aloe barbadensis leaf

extract

Package Label - Principal Display Panel



HAND SANITIZER SPRAY

Antiseptic Topical Solution

100 ml 3.3 FL OZ

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Distributed By: Clisen

Manufactured By: AIO Group California 91710



Drug Facts	
Active ingredient Ethyl alcohol 75% v/v.....	Purpose Antiseptic
Use Hand sanitizer spray 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 • on 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.	
Directions • Spray enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients aloe barbadensis leaf, benzalkonium chloride, dmdm hydantoin, glycerin, Vitamin E, water	

100 mL NDC: 75620-124-01

CLISEN			
sanitizer spray spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75620-124
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	GLYCERIN (UNII: PDC6A3C0OX)		
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
	DMDM HYDANTOIN (UNII: BYR0546TOW)		
	ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)		
	ALOE VERA LEAF (UNII: ZY81Z83H0X)		

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75620-124-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020	
2	NDC:75620-124-02	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/22/2020	

Labeler - Clisen (117493964)

Establishment

Name	Address	ID/FEI	Business Operations
AIO Group		105793933	manufacture(75620-124)

Revised: 8/2020

Clisen