

CLISEN- hand sanitizer gel

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 Gel

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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

Carbomer, FD&C Blue NO. 1, FD&C Red NO. 40, Propylparaben, Propyleneglycol, Purified Water,

Sodium Bicarbonate

Package Label - Principal Display Panel

Drug Facts

Active ingredient(s) Purpose • on children less than 2 months of age
Ethyl alcohol 75% v/v..... Antiseptic • on open skin wounds

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60 mL NDC: 75620-123-02

CLISEN			
hand sanitizer gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75620-123
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75620-123-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:75620-123-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:75620-123-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - Clisen (117493964)

Establishment

Name	Address	ID/FEI	Business Operations
AIO Group		105793933	manufacture(75620-123)

Revised: 5/2020

Clisen