

KLAREX CLEAR TM- alcohol antiseptic 62% topical solution solution
KLAREX CLEANSE TM- alcohol antiseptic 80 % topical solution solution
Hungaro-Gal Kft

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.

Drug Facts Active Ingredients

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 80% v/v.....	Antiseptic

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Active ingredient

Ethyl Alcohol 80% v/v.....

Prupose

Antiseptic

Use

Use	To kill germs on the skin which may cause disease - formulated for repeated use.
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Warnings

Warnings	For external use only. Flammable. Keep away from heat or flame.
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Do not use

Do not use <ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds

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When using this product

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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Keep Out of Reach of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

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- 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.

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Other Information

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

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Inactive Ingredients

Inactive ingredients Glycerin, Hydrogen Peroxide, Purified Water USP

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Indications and Usage

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Use for cleansing your hands when soap is not available

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Dosage and Administration**Dosage and Administration:**

wet hands thoroughly with product and allow to dry without wiping

Dosage and Administration: wet hands thoroughly with product and allow to dry without wiping

Principal Display Panel

KLAREX™

cleanse

Kills 99.9%
of germs



WHO-Recommended
Hand Sanitizer Formulation

Alcohol Antiseptic 80% | Topical Solution
Non-sterile Solution

e 33.8 FL OZ (1000ml)

HAND SANITIZER

Alcohol Antiseptic 80%

Topical Solution

Non-sterile Solution

e 33.8 FL OZ (1000ml)

Hand Sanitizer

who-recommended Hand Sanitizer Formulation

Kills 99.9% of germs

Klarex Clear Principal Display panel



Klarex Cler

Hand Sanitizer

KLAREX CLEAR TM

alcohol antiseptic 62% topical solution solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73753-622	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
TROLAMINE (UNII: 9O3K93S3TK)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
COCETH-7 (UNII: 58Y261JLH5)				
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)				
ISOPENTYLDIOL (UNII: 19NOL5474Q)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
WATER (UNII: 059QF0KO0R)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73753-622-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
2	NDC:73753-622-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
3	NDC:73753-622-03	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
4	NDC:73753-622-04	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
5	NDC:73753-622-05	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
6	NDC:73753-622-06	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	04/03/2020	

KLAREX CLEANSE TM	
alcohol antiseptic 80% topical solution solution	
Product Information	

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73753-821	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)		18.425 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73753-821-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
2	NDC:73753-821-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
3	NDC:73753-821-03	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
4	NDC:73753-821-04	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
5	NDC:73753-821-05	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
6	NDC:73753-821-06	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
7	NDC:73753-821-07	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	03/27/2020	

Labeler - Hungaro-Gal Kft (425075947)