NURINSE- hand sanitizer hocl liquid
NuGenTec

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NuRinse Hand Sanitizer HOCL Gel

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. HOCL 385ppm
b. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

HOCl solutions are already included in the WHO list of coronavirus-effective biocides, and in the US EPA 'N' list of disinfecting agents able to control emerging pathogens like SARS-CoV-2. 37,126 More than ten branded aqueous HOCl formulations have been cleared by the US FDA for topical use in wound management over the last decade. A Class III medical product approval for HOCl has been granted in the EU, and the Japanese Ministry of Health has approved use of HOCl for topical medical applications. The US FDA has approved HOCl for high level disinfection and sterilization of medical instruments, including those for use at critical (i.e., sterile) sites

Active Ingredient(s)

HOCL 385ppm 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

None

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.

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.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Avoid Direct Sunlight, store in an opaque bottle.
- Keep sealed when not in use.

Inactive ingredients

Purified water USP

Hydroxmethyl Cellulose

Package Label - Principal Display Panel

3785 mL NDC: 77368-386-01

NURINSE

hand sanitizer hocl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77368-386
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.000385 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	7 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Clear Color)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-386-05	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
2	NDC:77368-386-55	208198 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
3	NDC:77368-386-75	10409875 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
4	NDC:77368-386-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
5	NDC:77368-386-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
6	NDC:77368-386-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/05/2020	

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-386)

Revised: 12/2022 NuGenTec