HYPOCHLOROUS ACID- bactistop 100 liquid L'ENVOL PHARMA

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.

Active Ingredient(s)

Hypochlorous Acid 2% 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

water

Package Label - Principal Display Panel

100 mL NDC: 79394-100-01



HYPOCHLOROUS ACID

bactistop 100 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79394-100
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPO CHLO RO US ACID (UNII: 712K4CDC10) (HYPO CHLO RO US ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	2 mg in 100 mL

Inactive Ingredients

	Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)		

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:79394-100-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		03/30/2020			

Labeler - L'ENVOL PHARMA (362865293)

Registrant - L'ENVOL PHARMA (362865293)

Establishment			
Name	Address	ID/FEI	Business Operations
L'ENVOL PHARMA		362865293	manufacture(79394-100)

Revised: 7/2020 L'ENVOL PHARMA