

JASNA PEARL HAND SANITIZER- alcohol gel
ELLA COSMETIC CO., LTD.

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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 70%

PURPOSE

Purpose: SANITIZER

WARNINGS

Warnings:

For external use only.

1.Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema

2)Skin irritation symptoms

3.Other precautions

1) For external use only (do not swallow).

2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.

3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).
(Limited to ethanol-containing products)

4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.

5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.

6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.

7) Use only for the intended purposes.

4.Precautions for storage

1) Keep away from direct sunlight and do not expose the product to heating devices or flame.

2) Keep out of reach of children and go to the hospital immediately if swallowed.

3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality.
Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

Uses

Uses: Disinfection of hands and skin

Directions

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry.

INACTIVE INGREDIENT

Inactive ingredients:

WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, BUTYLENE GLYCOL, CAMELLIA SINENSIS LEAF EXTRACT, GLYCYRRHIZA URALENSIS(LICORICE) ROOT EXTRACT

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Jasna Pearl Hand Gel Sanitizer

99.9% Sterilization
Moisturizing to the skin

100ml(3.38 FL.OZ.)

Jasna Pearl Hand Gel Sanitizer

Drug Facts	
Active ingredients ALCOHOL 70%	Purpose SANITIZER
Uses Disinfection of hands and skin	
Warnings For external use only. 1. Do not use the product on the following areas: Around the eyes and ears, in the mouth, large body parts and damaged skin(irritation may occur) 2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. 1) Hypersensitivity symptoms, e.g.rash, erythema, itchiness, and edema 2) Skin irritation symptoms 3. Other precautions 1) For external use only (do not swallow). 2) Avoid contact with eyes, if contact occurs, wash with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale vapors in case of extended or prolonged use.(Repeating inhaling of large amount of ethanol vapor may cause irritation of the mucous membranes and headaches). 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. 7) Use only for the intended purposes.	
4 Precautions for storage 1) Keep away from direct sunlight and do not expose the product to heating devices or flame. 2) Keep out of reach of children and go to the hospital immediately if swallowed. 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container. Dust or foreign substances may get on the product while using it.	
Directions Take an appropriate amount on your hands and rub thoroughly to dry.	
Inactive ingredients WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, BUTYLENE GLYCOL, CAMELLIA SINENSIS LEAF EXTRACT, GLYCYRRHIZA URALENSIS(LICORICE) ROOT EXTRACT	
Ella Cosmetic Co., Ltd / www.ellacos.co.kr #1-202.10, Namdongdong-ro 33beon-gil, Namdong-gu, Incheon, Korea	
Net Wt: 100mL / 3.38 Fl. Oz.	
HDPE Made in Korea	

JASNA PEARL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74003-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74003-020-01	100 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - ELLA COSMETIC CO., LTD. (693714444)

Registrant - ELLA COSMETIC CO., LTD. (693714444)

Establishment			
Name	Address	ID/FEI	Business Operations
ELLA COSMETIC CO., LTD.		693714444	manufacture(74003-020)