ESCO FRESH PURE HAND- alcohol gel Arca Inc.

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 70.00%

INACTIVE INGREDIENT

Inactive ingredients: Water, Butylene Glycol, Carbomer, PEG-60 Hydrogenated Castor Oil, Triethanolamine, Fragrance

PURPOSE

Purpose: SANITIZER, Antiseptic

WARNINGS

Warnings:

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)

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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.

PACKAGE LABEL - ESCO FRESH PURE HAND GEL 35mL * 20ea, Carton



PACKAGE LABEL - ESCO FRESH PURE HAND GEL 500mL, Bottle



ESCO FRESH alcohol gel	I PURE HA	ND						
Product Inform	ation							
Product Type	HUMAN OTC DRUG Item Code (Source)		e (Source)	NDC:19339-020				
Route of Administr	ration	TOPICAL						
Active Ingredie	nt/Active Moi	ety						
		lient Name		Basis of Strength		Strength		
ALCOHOL (UNII: 3K	•	COHOL - UNII:3K9958V90M)		ALCOHOL		g in 100 mL		
Inactive Ingred	ients							
				Strength				
Water (UNII: 059QF0KO0R)								
Butylene Glycol (UNII: 3XUS85K0RA)								
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)								
PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)								
TROLAMINE (UNII:	9038935318)							
Packaging								
# Item Code		Package Description		Marketing Start Date	Ma	rketing End Date		
1 NDC:19339-020- 02	20 in 1 CARTON			03/01/2020				
1 NDC:19339-020- 01	35 mL in 1 POUC	n 1 POUCH; Type 0: Not a Combination Product						
2 NDC:19339-020- 03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			03/01/2020				
Marketing In	formation							
Marketing Categ	ory Applicat	ion Number or Monograph C	itation N	Marketing Start Date	Mark	eting End Date		

03/01/2020

Labeler - Arca Inc. (688522453)

Registrant - Arca Inc. (688522453)

Establishment							
Address	ID/FEI	Business Operations					
	688425766	manufacture(19339-020)					
	Address						

Revised: 4/2020

Arca Inc.