ADVANCE HAND SANITIZER MOISTURIZING FORMULA WITH ALOE AND VITAMIN E- alcohol gel All Pharma LLC

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

Isopropyl Alcohol 70.0%

Purpose

Antimicrobial

Uses

To help decrease bacteria on the skin. Recommended for repeat use.

Warnings

For external use only.

Flammable. Keep away from heat and flame.

When using this product

- Keep out of eyes. In case of contact, rinse eyes thoroughly with water
- Avoid contact with broken skin
- Do not inhale or ingest

Stop use and ask a doctor if

If irritation or redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision
- Not recommended for infants

Inactive ingredients

aloe barbadensis powder, amino-methyl-propanol, carbomer, glycerin, isopropyl myristate, propylene glycol, tocopheryl acetate, water



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alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:53149-1100	
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	

ı	nactive Ingredients	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53149- 1100-3	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
2	NDC:53149- 1100-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
3	NDC:53149- 1100-2	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
4	NDC:53149- 1100-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
5	NDC:53149- 1100-8	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
6	NDC:53149- 1100-5	3790 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
OTC monograph not final	part333E	01/01/2020	

Labeler - All Pharma LLC (117605075)

Registrant - All Pharma LLC (117605075)

Establishment				
Name	Address	ID/FEI	Business Operations	
All Pharma LLC		117605075	manufacture(53149-1100)	

Revised: 4/2019 All Pharma LLC