

ARSOMI HAND SANITIZER- alcohol gel ESON

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.

Drug Facts

alcohol

ethanol, water, glycerin, polysorbate 80, carbomer, aloe arborescens leaf extract, triethanolamine, tocopheryl acetate

Sterilization of hands and skin

KEEP OUT OF REACH OF THE CHILDREN

Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.

Supervise children in the use of this product.

- Flammable. Keep away from fire or flame.
- For external use only.
- Do not use in eyes.
- If swallowed, get medical help promptly.
- Stop use, ask doctor if irritation occurs.
- Keep out of reach of children.

for external use only

ARSOMI HAND SANITIZER

Drug Facts	
Active ingredients	Purpose
Ethyl alcohol 70.0% w/v	Antiseptic
Uses	
<ul style="list-style-type: none"> Hand sanitizer to decrease bacteria on the skin that could cause disease. 	
Warnings	
For external use only-hands	
Flammable. Keep away from heat and flame.	
When using this product	
<ul style="list-style-type: none"> Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest. 	
Stop use and ask a doctor if Skin irritation or rash develops.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> Take an appropriate amount on your hands and rub thoroughly to dry. For children under 6, use only under adult supervision. Not recommended for infants. 	

ARSOMI HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76677-0002
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
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76677-0002-1	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - ESON (689575314)

Registrant - ESON (689575314)

Establishment

Name	Address	ID/FEI	Business Operations
ESON		689575314	manufacture(76677-0002)

Revised: 4/2020

ESON