WELLNICITY HAND SANITIZER- alcohol gel
United Laboratories Manufacturing, 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.

Wellnicity Hand Sanitizer

Active ingredients

Ethyl Alcohol 70.0% v/v

Purpose

Anti Microbial

Warnings

Flammable: keep away from excessive heat or open flame.

For external use only.

Do not use

in or near eyes. In case of eye contact, flush with water. Do not apple to open wounds or damaged skin.

Keep out of reach of children.

Stop use and consult a doctor

if irritation occurs.

Directions

- Aplly entire packet to palm of hand. Use no water or towels. Rub until hands are completely covered.

Inactive ingredients

Distilled Water, Biopol Plus / Carbomer 940, Aloe Vera Aqueous Extract, Aminomethyl Propane, Rapidgel.

Uses

- Hand sanitizer helps reduce bacteria on the skin could cause disease.

Product Label

C:\Users\RegCorp 142\Downloads\Download SPL\Listings to submit to FDA\United Laboratories Manufacturing, LLC (73009-017) Wellnicity Hand Sanitizer

WELLNICITY HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62400-0017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62400-0017-1	1000 in 1 BOX	07/30/2020	
1		2.25 mL in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/30/2020	

Labeler - United Laboratories Manufacturing, LLC (807878116)

Establishment

Name	Address	ID/FEI	Business Operations
Dibar Nutricional, S. de R.L. de C.V.		812786543	manufacture(62400-0017) , label(62400-0017) , pack(62400-0017)

Revised: 7/2020 United Laboratories Manufacturing, LLC