

HYGIENE PLUS HAND SANITIZER- alcohol gel

WILSHIRE LABORATORIES PRIVATE LIMITED

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.

Hygiene Plus Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

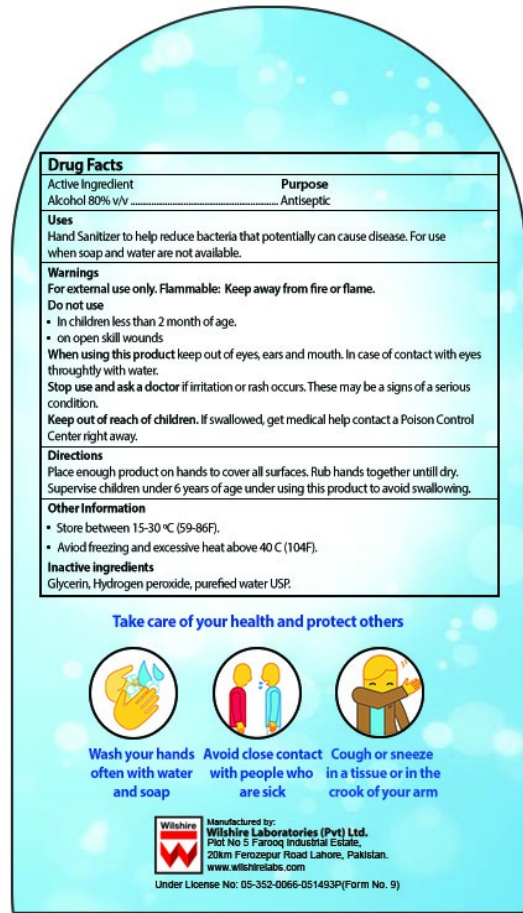
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Front

Back



35mm

35mm

60 mL NDC: 78813-060-80

HYGIENE PLUS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78813-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	50 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.096 mL in 60 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.151 mL in 60 mL
WATER (UNII: 059QF0KO0R)	6.219 mL in 60 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78813-060-80	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Front

Back

62mm

60ml
Hygiene+
HAND SANITIZER
Gel

NDC NO. 78813-060-80
Mfg. Date: APR 2020
Best Before: APR 2022
Once open use within 30 days

Imported by:
Lá Originale Corp. U.S.A.
La Originale Rockwell Center,
NY11570
Tollfree No. 1-888-345-7473

35mm

62mm

Drug Facts	
Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic
Uses Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable: Keep away from fire or flame. Do not use • In children less than 2 month of age. • on open skill wounds When using this product keep out of eyes, ears and mouth. In case of contact with eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. These may be a signs of a serious condition. Keep out of reach of children. If swallowed, get medical help contact a Poison Control Center right away.	
Directions Place enough product on hands to cover all surfaces. Rub hands together untill dry. Supervise children under 6 years of age under using this product to avoid swallowing.	
Other Information • Store between 15-30 °C (59-86F). • Avoid freezing and excessive heat above 40 °C (104F).	
Inactive ingredients Glycerin, Hydrogen peroxide, purified water USP.	

Take care of your health and protect others

Wash your hands often with water and soap Avoid close contact with people who are sick Cough or sneeze in a tissue or in the crook of your arm

Manufactured by:
Wilshire Laboratories (Pvt) Ltd.
Plot No 5 Farooq Industrial Estate,
20km Ferozpur Road Lahore, Pakistan.
www.wilshirelabs.com
Under License No: 05-352-0066-051493P(Form No. 9)

35mm

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - WILSHIRE LABORATORIES PRIVATE LIMITED (645383407)

Registrant - WILSHIRE LABORATORIES PRIVATE LIMITED (645383407)

Establishment

Name	Address	ID/FEI	Business Operations
WILSHIRE LABORATORIES PRIVATE LIMITED		645383407	manufacture(78813-060)

