

NOWAVE HAND SANITIZER- hand sanitizer gel
NOWAVE 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.

DRUG FACTS LABEL

Drug Facts Active ingredient[s] Purpose Alcohol 80% v/v.....Antiseptic
.....Antiseptic
Use[s] 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. 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

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

Alcohol 80% v/vAntiseptic

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. this may be a sign of a serious condition.

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

Glycerin, hydrogen peroxide, purified water USP

Use(s)

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

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

Directions

place enough product on hands to cover all surfaces. Rub hands together until dry.
Supervise Children under 6 years of age to prevent swallowing.

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution [Insert Volume of Product in mL



NOWAVE HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74036-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	48 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.075 mL in 60 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.87 mL in 60 mL
WATER (UNII: 059QF0K00R)	11.12 mL in 60 mL

Product Characteristics

Color	white (clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74036-001-02	60 mL in 1 BOTTLE, PLASTIC; 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	03/27/2020	

Labeler - NOWAVE LLC (112797757)

Registrant - NOWAVE LLC (822815047)

Establishment

Name	Address	ID/FEI	Business Operations
NOWAVE LLC		112797757	manufacture(74036-001)

Revised: 3/2020

NOWAVE LLC