GENRX ANTI-BACTERIAL GEL- alcohol liquid
PureTek Corporation

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.

GENRX unfragranced ANTI-BACTERIAL GEL- alcohol liquid

Active Ingredient

Alcohol 62% (v/v)

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable. Keep away from fire or flame.

When using this product

do not use in or near eyes. In case of contact, rinse eyes throughly with water

Stop use and ask a doctor if

If irritation or rash appears and lasts.

Keep out of reach of children

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

Directions

■ Dispense and rub onto hands until dry. Do not rinse off.

■ Children under 6 years of age should use this product under supervision.

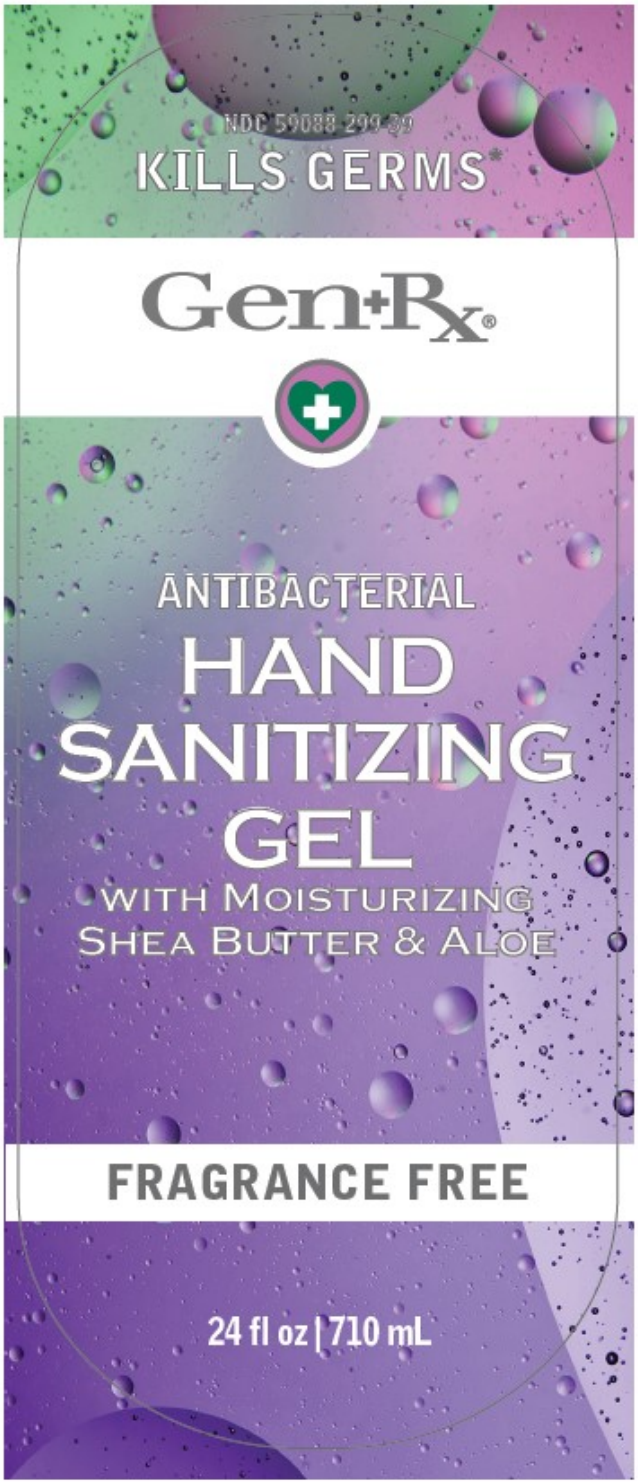
Other information

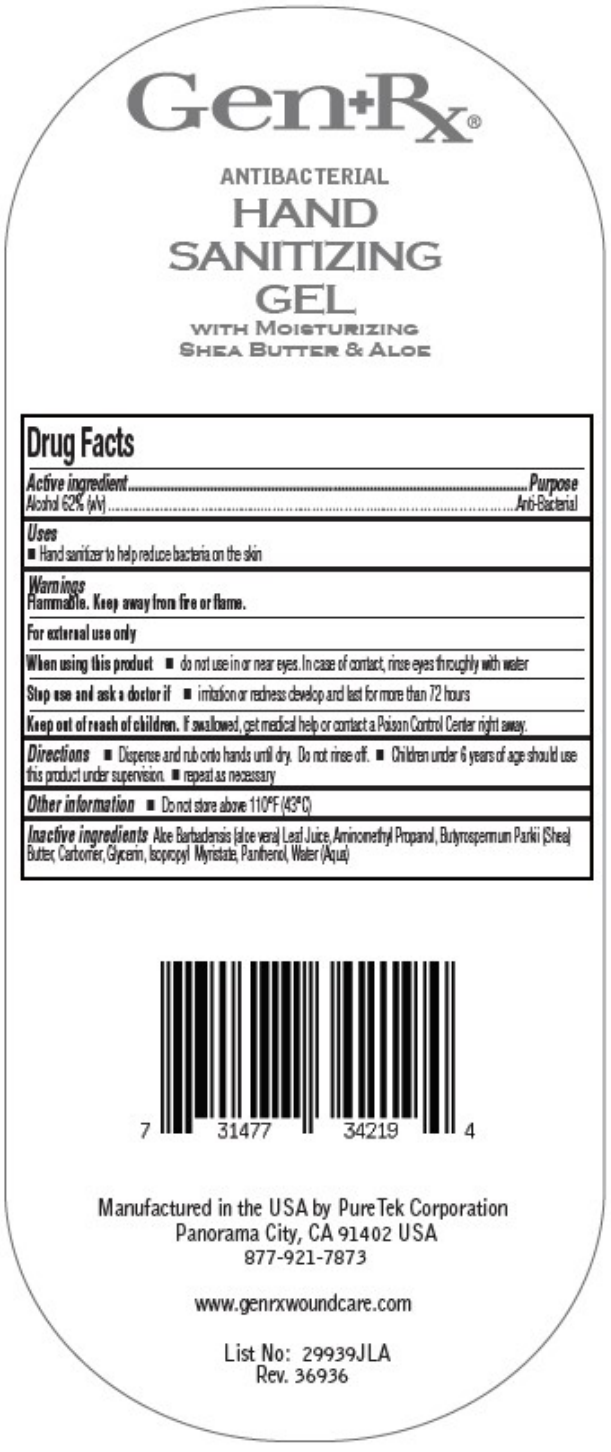
■ Do not store above 110°F (43°C)

Inactive ingredients

Aloe Barbadensis (aloe vera) Leaf Juice, Aminomethyl Propanol, Butyrospermum Parkii (Shea) Butter, Carbomer, Glycerin, Isopropyl Myristate, Water (Aqua)

GenRx Hand Sanitizing Gel (24 fl oz)





GENRX ANTI-BACTERIAL GEL

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-299
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SHEA BUTTER (UNII: K49155WL9Y)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-299-48	710 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/18/2020	05/11/2020
2	NDC:59088-299-08	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/18/2020	
3	NDC:59088-299-31	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/18/2020	
4	NDC:59088-299-39	710 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/18/2020	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-299)