HAND SANITIZER FRESH- benzalkonium chloride gel Harmonia de Venezuela CA

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

Active Ingredient

Purpose

Benzalkonium Chloride (0.1 %)----- Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin.

Warnings

For external uses only. / **When using this products** avoid contact of eyes. In case of eye contact, flush eyes with water. / **Stop use and ask a doctor if** irritation or redness develops, or if conditions persists for more than 72 hours. /**Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply a small amount into palm of hands and rub hands together briskly until dry.

Inactive Ingredients

water, glycerin, hydroxypropyl methylcellulose, PEG-12 dimethicone, fragance, DMDM hydantoin, FD&C Blue No. 1

Principal display panel





SANITIZE YOUR HANDS ANYWHERE!









Net. Cont. 0.94 fl oz. (28 ml)



Kills 99.99% of germs in 15 seconds

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Each 0.10 Fl Oz. (3 ml)

SACHETS



CONVENIENT HAND SANITIZER GEL OF FAST ABSORPTION AND FRESH FRAGANCE, In the perfect size to take it wherever you go.

CONVENIENTE GEL ANTIBACTERIAL DE RÁPIDA ABSORCIÓN Y FRESCA FRAGANCIA, en el tamaño perfecto para llevarlo a donde vayas.



KILLS 99.99% OF GERMS IN LESS THAN 30 SECONDS / ELIMINA EL 99.99% DE LOS GÉRMENES EN MENOS DE 30 SEGUNDOS.

DRUGS FACTS			
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SANITIZE YOUR HANDS ANYWHERE!

HAND SANITIZER FRESH

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73360-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6 JUD5X6 Y) BENZALKONIUM 1 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)		
DMDM HYDANTO IN (UNII: BYR0546 TOW)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73360-003-01	4 in 1 CARTON	09/20/2019	
1		28 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73360-003-02	100 in 1 CARTON	09/20/2019	
2		3 mL in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:73360-003-03	28 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/20/2019	

Labeler - Harmonia de Venezuela CA (817307290)

Establishment				
Name	Address	ID/FEI	Business Operations	
Harmonia de Venezuela CA		817307290	manufacture(73360-003)	

Revised: 9/2019 Harmonia de Venezuela CA