

HYGENIX AF GEL- benzalkonium chloride gel
GM Industrial, Inc.

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

Benzalkonium chloride 0.1%

Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin.

Recommended for repeated use.

For external use only

When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition 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

- Pump a small amount of gel into palm of hand
- Rub thoroughly over all surfaces of both hands
- Rub hands together briskly until dry.

Water, carbomer, glycerin, lactic acid.

74146-244-02

23494

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cp





Alcohol-Free Hand Sanitizer

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.1%.....

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Inactive Ingredients

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6.76 FL OZ (200 mL)

ZENEX INTERNATIONAL

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LOT
EXP

HYGENIX AF GEL

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74146-244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LACTIC ACID (UNII: 33X04XA5AT)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74146-244-03	24 in 1 BOX	10/05/2021	
1	NDC:74146-244-02	200 mL in 1 CONTAINER; 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	part333A	10/05/2021	

Labeler - GM Industrial, Inc. (025827197)**Establishment**

Name	Address	ID/FEI	Business Operations
GM Industrial, Inc.		025827197	manufacture(74146-244) , pack(74146-244) , label(74146-244) , repack(74146-244) , relabel(74146-244)

