

**GERMISEPT ANTIBACTERIAL HAND SANITIZING WIPES- benzalkonium chloride liquid
Innovent 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.

GERMISEPT Antibacterial Hand Sanitizing Wipes

Active Ingredient

Benzalkonium Chloride 0.12%

Purpose

Antibacterial

Uses

Decrease bacteria on the skin.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Discontinue use if

irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

- Open resealable label, remove one wipe to use.
- Wipe hands thoroughly with product and allow to dry without wiping.
- Close resealable label after use to retain moisture.

Other information

- Store below 95° F (35° C) to prevent from drying out.

- Dispose of wipe in the proper container.
- Do not flush down the toilet.

Inactive ingredients

Aqua (Purified & De-Ionized Water), Aloe Barbadensis Leaf Extract, Citric Acid, Didecyldimonium Chloride, 2-Bromo-2-Nitropropane-1,3-Diol, Polyaminopropyl Biguanide, Parfum (Fragrance).

Package Labeling:



GERMISEPT ANTIBACTERIAL HAND SANITIZING WIPES

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70335-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE SODIUM (UNII: MP1J8420LU)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70335-301-08	8 in 1 PACKAGE	09/06/2016	11/30/2025
1		30 g in 1 PATCH; 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	part333E	09/06/2016	11/30/2025

Labeler - Innovent Inc. (079973489)

Registrant - American Hygienics Corporation (545198454)

Establishment

Name	Address	ID/FEI	Business Operations
American Hygienics Corporation		545198454	manufacture(70335-301)

Revised: 1/2023

Innovent Inc.