ZYTEC GERM BUSTER HAND SANITIZER- ethanol gel
Empack

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 for an OTC Hand Sanitizer

Active Ingredient

Ethyl Alcohol 65%

Purpose

Antiseptic

- For handwashing to decrease bacteria on the skin
- Recommended for repeat use

Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use in the eyes. In case of contact rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and 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.

- wet hands thoroughly with product
- briskly rub hands together until dry
- supervise children in the use of this product
- wet hands generously with product, rub hands together gently until dry.

Other Information

- store at 20º to 25º (68º to 77ºF)
- may discolor fabrics

Inactive Ingredients

Aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), isopropyl alcohol,

aminomethyl propanol, carbomer, glycerin, isopropyl myristate, propylene glycol,

methyl gluceth-10, polysorbate 20, fragrance, water.

Product Labels

MM1

Front

Color: cyan, pms 288, pms 032, BackgroundWhite
(Print White ink, pink colour just for view)

Front(BackgroundWhite only)

Color: BackgroundWhite
(Print White ink, pink colour just for view)

Back

Color: pms 288,
BackgroundWhite
(Print White ink, pink colour just for view)

ZYTEC GERM BUSTER HAND SANITIZER

ethanol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50021-065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ETHANOL (UNII: 3K9958V90M) (ETHANOL - UNII:3K9958V90M)	ETHANOL	143 g in 238 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50021-065-01	238 g in 1 BOTTLE, PUMP		
2	NDC:50021-065-02	52 g in 1 BOTTLE, PLASTIC		
3	NDC:50021-065-03	104 g in 1 BOTTLE, PLASTIC		
4	NDC:50021-065-04	908 g in 1 BOTTLE, PUMP		
5	NDC:50021-065-05	475 g in 1 BOTTLE, PUMP		
6	NDC:50021-065-06	713 g in 1 BOTTLE, PUMP		
7	NDC:50021-065-07	908 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/28/2011	

Labeler - Empack (252047519)

Registrant - Empack (252047519)

Establishment

Name	Address	ID/FEI	Business Operations
Empack		252047519	manufacture

Revised: 1/2011 Empack