

JENNY HOUSE HAND PROTECTOR- alcohol gel

Jennyhouse cosmetics

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

Alcohol

Water, Carbomer, Fragrance(Parfum), Aminomethyl Propanol, Glycerin, Butylene Glycol, Propylene Glycol, Aloe Barbadensis Leaf Extract, Phenoxyethanol, Ethylhexylglycerin

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin

KEEP OUT OF REACH OF THE CHILDREN

Pump an appropriate amount on to the hands and rub together until dry

1. Do not use this product on the following parts of body. Around eyes and ears, oral cavity, large area of the parts of body, or wounded skins (It may cause irritations)
 2. Stop using at once in case of the following symptoms, and seek medical advice. 1) When eczema, red spots, itchiness, edema, and allergic reactions occur. 2)When skin irritations happen.
 3. Other user reminders 1) For external use only(No oral intake). 2) Avoid contact with eyes, and in case contact occurs, rinse it thoroughly with clean water and consult a doctor or pharmacist. 3) When you use it on a large skin area or use it long-termly, please be aware that vapor is not absorbed. (If Ethanol vapor is largely and repeatedly inhaled and absorbed, it may cause irritation to mucous membrane and headache might occur.) 4)When the product is used on the same part of skin repeatedly, the skin may become rough due to skimming. 5) Do not use with sealed gauze bandage, Gibbs bandage or pack, as irritations may occur. 6) Do not use this product while anus and vagina steaming as irritations or chemical burns may occur. 7) Do not use for purposes other than specified.
- external use only

Drug Facts	
Active Ingredients	Purpose
Ethanol (Synthetic Alcohol) 58% -----	Disinfecting Agent
Uses	
<ul style="list-style-type: none"> ■ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease ■ instant hand antiseptic to decrease bacteria on the skin 	
Warning	
For external use only When using this product <ul style="list-style-type: none"> ■ if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes ■ Stop immediately and consult a doctor if you experience <ol style="list-style-type: none"> 1) Hypersensitivity symptoms such as erythema, itching and dermatitis. 2) Skin Irritation 3) Following Instructions when using medication <ol style="list-style-type: none"> (1) For external use only (Do not use internally) (2) Avoid getting into the eyes (if contact occurs, wash well with clean water) ■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur. ■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage. ■ Do not use in combination with soap or antibacterial cleansing agents. 	
Directions	
<ul style="list-style-type: none"> ■ Pour a small amount into hands, spread evenly and rub into the skin 	
Other Information	
<ul style="list-style-type: none"> - read the directions and warnings before use - avoid freezing and excessive heat above 40 degree C (104 degree F) 	
Inactive Ingredients	
Water, Carbomer, Fragrance(Parfum), Aminomethyl Propanol, Glycerin, Butylene Glycol, Propylene Glycol, Aloe Barbadensis Leaf Extract, Phenoxyethanol, Ethylhexylglycerin	
Questions or Comments? Call +82-2-515-7115	

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JENNY HOUSE HAND PROTECTOR			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78045-0001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78045-0001-2	470 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/06/2020	

Labeler - Jennyhouse cosmetics (695831662)

Registrant - Jennyhouse cosmetics (695831662)

Establishment

Name	Address	ID/FEI	Business Operations
Jennyhouse cosmetics		695831662	manufacture(78045-0001) , label(78045-0001)

Revised: 6/2020

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