CELLAPY DR SANITIZER 25ML- alcohol gel GM Holdings Co., Ltd

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

ACTIVE INGREDIENT: Ethanol (Synthetic Alcohol 65.3%)

INACTIVE INGREDIENT

INACTIVE INGREDIENT:

Glycerin, Carbomer, Trolamine, Fragrance, Water

PURPOSE

PURPOSE: Disinfecting Agent

KEEP OUT OF REACH OF CHILDREN

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Uses:

Uses: Externally disinfects the hands and skin

WARNINGS

Warnings:

For external use only

When using this product if following abnormal symptoms persist, discontinue use

1) 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

- 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.
- 2) Skin Irritation
- 3) Following Instructions when using medication
- 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 to not 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 may occur or sickness 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.

Precautions

- 1) Keep out of open flames
- 2) Keep out of reach of children
- 3) Do not replace the container with another as quality deterioration or accidents may occur

Directions

Directions:

Pour a small amount onto hands, spready evenly and rub into skin

PACKAGE LABEL - Cellapy Dr Sanitizer 25mL

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CELLAPY DR SANITIZER 25ML

Active Ingredient/Active Moiety

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69278-111
Route of Administration	TOPICAL		

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	16.32 g in 25 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)			
Trolamine (UNII: 9O3K93S3TK)			
Water (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69278-111- 01	25 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/04/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/04/2020		

Labeler - GM Holdings Co., Ltd (688439958)

Registrant - GM Holdings Co., Ltd (688439958)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kukbo Science Co., Ltd.		687792812	manufacture(69278-111)	

Revised: 3/2020 GM Holdings Co., Ltd