

PURUS ANTIBACTERIAL WIPES- glyceryl laurate, levulinic acid, caprylhydroxamic acid, alcohol cloth

The fab Korea 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.

The fab Korea Co., Ltd. - Purus antibacterial wipes

glyceryl laurate, laurylpyridinium chloride, caprylhydroxamic acid, alcohol, levulinic acid
sodium coco pg-dimonium chloride phosphate, sodiu levulinate, methyl propanediol, water

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

keep out of reach of the children

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

for external use only

DrugFacts	
Active Ingredient	Purpose
Glyceryl laurate 0.08%.....	auxiliary Antiseptic
Alcohol 0.02%.....	Antiseptic
Caprylhydroxamic acid 0.02%.....	auxiliary Antiseptic
Levulinic acid 0.05%.....	auxiliary Antiseptic
Use	
for hand-washing to decrease bacteria on the skin, only when water is not available	
Warnings	
Flammable, keep away from fire and flames For external use only	
When using this product	
■ do not get into eyes	
■ if contact occurs, rinse eyes thoroughly with water	

- If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

Keep out of reach of children.

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

Directions

- Whenever and wherever you want to wash your hands, you can pull out a sheet and wash your hands or wipe the area where your hands reach.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

water, Glyceryl laurate, Laurylpyridinium chloride, Caprylhydroxamic acid, Levulinic acid, Sodium leveulate, Sodium coco pg-dimonium chloride phosphate, Methylpropanediol,

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PURUS ANTIBACTERIAL WIPES

glyceryl laurate, levulinic acid, caprylhydroxamic acid, alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77504-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERYL LAURATE (UNII: Y98611C087) (GLYCERYL LAURATE - UNII:Y98611C087)	GLYCERYL LAURATE	0.0448 g in 56 g
LEVULINIC ACID (UNII: RYX5QG61E1) (LEVULINIC ACID - UNII:RYX5QG61E1)	LEVULINIC ACID	0.028 g in 56 g
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) (CAPRYLHYDROXAMIC ACID - UNII:UPY805K99W)	CAPRYLHYDROXAMIC ACID	0.0112 g in 56 g
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.0112 mL in 56 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77504-0004-1	56 g in 1 PACKAGE; Type 0: Not a Combination Product	09/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/02/2020	

Labeler - The fab Korea Co., Ltd. (694885775)

Registrant - The fab Korea Co., Ltd. (694885775)

Establishment

Name	Address	ID/FEI	Business Operations
The fab Korea Co., Ltd.		694885775	manufacture(77504-0004)

Revised: 9/2020

The fab Korea Co., Ltd.