IMU- lactobacillus helveticus, rice bran aerosol, foam RAPHAGEN CO. LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

Active Ingredient: LACTOBACILLUS HELVETICUS 1.00 %, RICE BRAN 1.00%

INACTIVE INGREDIENT

Inactive Ingredients: Water(Aqua), Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Alcohol, Propanediol, Paeonia Suffruticosa Root Extract, Allantoin, Centella Asiatica Extract, Sodium Chloride, Hydroxyacetophenone, PEG-60 Hydrogenated Castor Oil, Lactic Acid, Menthol, Disodium EDTA, Fragrance(Parfum)

PURPOSE

Purpose: Sanitizer

WARNINGS

Warnings: 1. In case of having following symptoms after using this product, stop using it immediately. If the symptoms get worse, you need to consult a dermatologist. 1) In case of having problems such as red spots, swelling, itching or irritation during using this product 2) In case of having the same symptoms above on the part where you put this product, which is exposed to direct sunlight. 2. Do not use it on the part where you have a scar, eczema or dermatitis. 3. Topical use only 4. Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN

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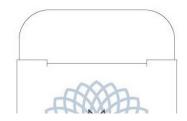
INDICATIONS & USAGE

Indications & usage: 1. Two or three times the pump out less on the palm of the press an adequate amount of foam. 2. Rub gently massage it in as along the external genitals and anal. 3. Rinse with tepid water well. 4. You can use every day. 1 day more than three times.

DOSAGE & ADMINISTRATION

Dosage & Administration: Two or three times the pump out less on the palm of the press an adequate amount of foam.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





IMU

lactobacillus helveticus, rice bran aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71125-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LACTOBACILLUS HELVETICUS (UNII: Q08Z44662J) (LACTOBACILLUS HELVETICUS - UNII:Q08Z44662J)	LACTOBACILLUS HELVETICUS	1.50 g in 150 mL	
RICE BRAN (UNII: R60 QEP13IC) (RICE BRAN - UNII:R60 QEP13IC)	RICE BRAN	1.50 g in 150 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Glycerin (UNII: PDC6A3C0OX)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:71125-010-	1 in 1 CARTON	12/0 1/20 16	
1 NDC:71125-010- 01	150 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		12/01/2016		

Labeler - RAPHAGEN CO. LTD (689852157)

Registrant - RAPHAGEN CO. LTD (689852157)

Establishment			
Name	Address	ID/FEI	Business Operations
RAPHAGEN CO. LTD		689852157	manufacture(71125-010)

Revised: 1/2017 RAPHAGEN CO. LTD