

**LACTOMEDI SELF-CARE TRIAL KIT- lactobacillus ferment lysate
2359 US INC**

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.

83490-901 Lactomedi Self-care Trial Kit

Active Ingredients

Lactobacillus Ferment Lysate

Purposes

BACTERIOSTATIC

Uses

Maintain your natural pH balance and keep your intimate area moist.

Warnings

Do not use it on the part where you have a scar, eczema, or dermatitis.

Do not suitable for children under 3 years of age

Warnings

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Warnings

Stop use and ask a doctor if irritation, rash, red spot on the skin, or swelling occurs. These may be signs of a severe condition.

Warnings

After opening the cap, use the product immediately and do not reuse it. Women in gestational periods should better not use it and not use it on the vulva just before delivery.

Women in gestational periods should better not use it and not use it on the vulva just before delivery.

Warnings

After opening the cap, use the product immediately and do not reuse it.

Directions

After washing your hands, open the package, remove the cap, and apply it to the intimate area as if it were an injection.

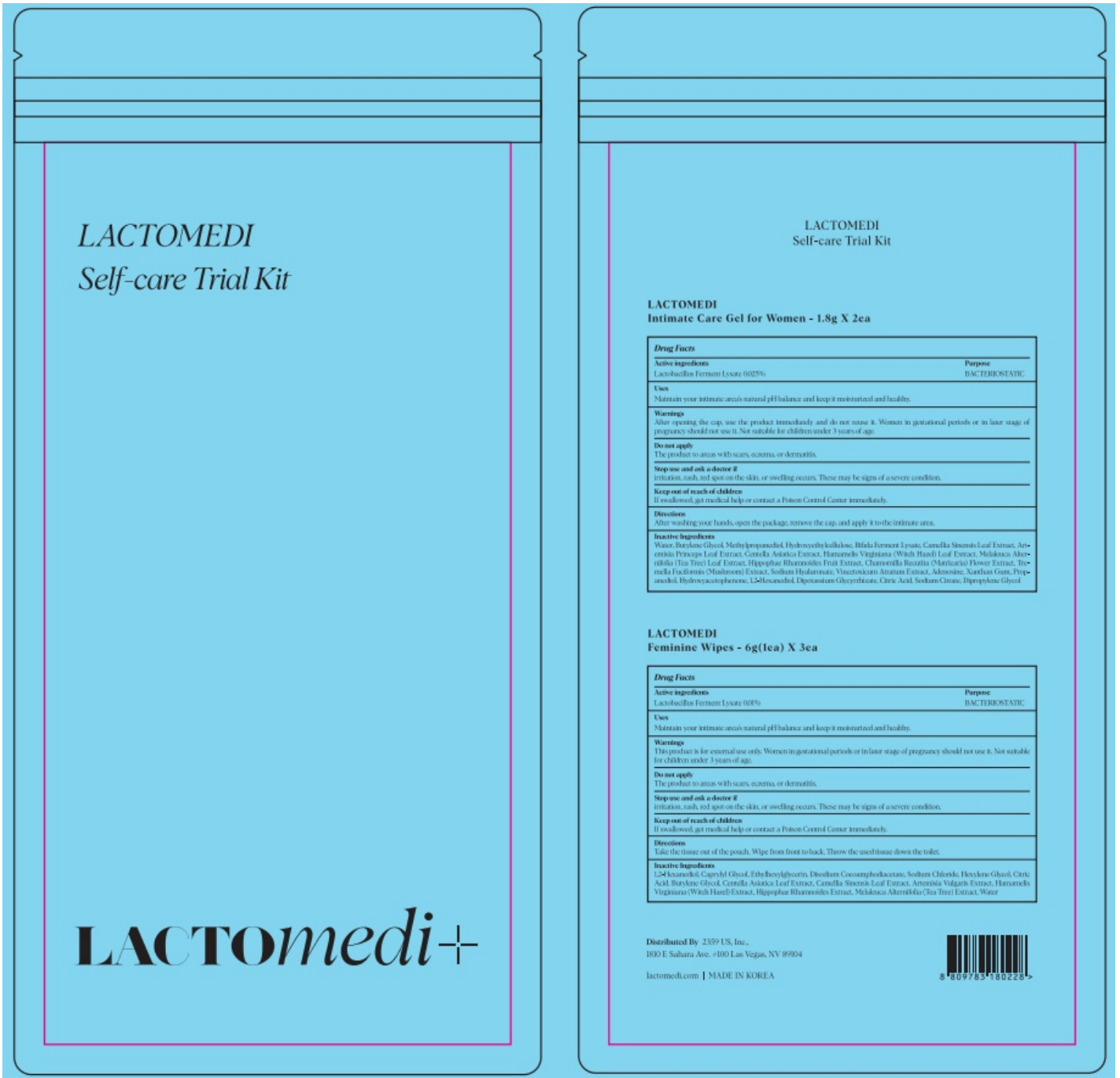
Take the tissue out of the pouch. Wipe the are from front to back. Throw tissue s in the toilet.

Inactive Ingredients

Water, Butylene Glycol, Methylpropanediol, Hydroxyethylcellulose, Bifida Ferment Lysate, Camellia Sinensis Leaf Extract, Artemisia Princeps Leaf Extract, Centella Asiatica Extract, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Extract, Hippophae Rham- noides Fruit Extract, Chamomilla Recutita (Matricaria) Flower Extract, Tre- mella Fuciformis (Mushroom) Extract, Sodium Hyaluronate, Vincetoxicum Atratum Extract, Adenosine, Xanthan Gum, Propanediol, Hydroxyacetoph enone,1,2-Hexanediol, Dipotassium Glycyrrhizate, Citric Acid,Sodium Citr- ate, Dipropylene Glycol

1,2-Hexanediol, Caprylyl Glycol, Ethylhexylglycerin, Disodium Cocoamphodiace- tate, Sodium Chloride, Hexylene Glycol, Citric Acid, Butylene Glycol, Centella Asiatica Leaf Extract, Camellia Sinensis Leaf Extract, Artemisia Vulgaris Extract, Hamamelis Virginiana (Witch Hazel) Extract, Hippophae Rhamnoides Extract, Melaleuca Alternifolia (Tea Tree) Extract, Water

Label



LACTOMEDI SELF-CARE TRIAL KIT

lactobacillus ferment lysate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83490-901
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83490-901-01	1 in 1 KIT; Type 0: Not a Combination Product	04/01/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOX, UNIT-DOSE	90 g in 100
Part 2	0 BOTTLE, PLASTIC	1.8 g in 100

Part 1 of 2

LACTO REMEDY LADYS CLEANSING WIPES

lactobacillus ferment lysate swab

Product Information

Item Code (Source)	NDC:82892-302
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIMOSILACTOBACILLUS FERMENTUM ME-3 (UNII: BQX4W45LG8) (LIMOSILACTOBACILLUS FERMENTUM ME-3 - UNII:BQX4W45LG8)	LIMOSILACTOBACILLUS FERMENTUM ME-3	0.01 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
MELALEUCA ALTERNIFOLIA WHOLE (UNII: 976KV4FXYP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82892-	90 q in 1 BOX, UNIT-DOSE; Type 0: Not a		

302-01	Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2023	

Part 2 of 2

LACTO REMEDY LADYS INNER CARE GEL

lactobacillus ferment lysate solution, gel forming / drops

Product Information

Item Code (Source)	NDC:82892-304
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIMOSILACTOBACILLUS FERMENTUM ME-3 (UNII: BQX4W45LG8) (LIMOSILACTOBACILLUS FERMENTUM ME-3 - UNII:BQX4W45LG8)	LIMOSILACTOBACILLUS FERMENTUM ME-3	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TREMELLA FUCIFORMIS WHOLE (UNII: 4938BNS0GU)	
VINCETOXICUM ATRATUM WHOLE (UNII: U3176B0S5J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	
WATER (UNII: 059QF0KO0R)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
CHAMOMILE (UNII: FGL3685T2X)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)	
ACONITIC ACID (UNII: 93371T1BXP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPANEDIOL (UNII: 5965N8W85T)	

ADENOSINE (UNII: K72T3FS567)

1,2-HEXANEDIOL (UNII: TR046Y3K1G)

GREEN TEA LEAF (UNII: W2ZU1RY8B0)

GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82892-304-01	18 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2023	

Labeler - 2359 US INC (118974080)

Registrant - 2359 US INC (118974080)

Establishment

Name	Address	ID/FEI	Business Operations
isamogu Inc.		695695834	manufacture(83490-901)

Revised: 4/2023

2359 US INC