

**REPUERA DERMATOZYME 5% HYDRO ESSENTIAL AMPULE- allantoin,
glycerin liquid
ALLUV**

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.

81459-303 re'puera DermAtozyme 5% Hydro Essential Ampule

Active Ingridients

Glycerin (15%)

Allantoin (0.01%)

Purpose

skin protectant

Uses

Organizing water-oil balance.

Micro-encapsulated oil and water gives glow and balances to the broken skin barrier.

Warnings

For external use only

keep away from heat.

When using this product

keep out of eyes.

Stop use and ask a doctor if

irritation or rash occurs.

Keep out of reach of children.

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Directions

Apply an appropriate amount of drops

to the damaged skin and massage in as a leave on treatment. Gently tap for absorption. Use daily or as often as needed.

Other Information

STORE AT ROOM TEMPERATURE

Inactive Ingredients

Water, Diphenyl Dimethicone, Dendropanax Morbiferus Extract, Ceramide NP, Cyanocobalamin, Sodium Hyaluronate, Copper Tripeptide-1, Tripeptide-1, Palmitoyl Pentapeptide-4, Oligopeptide-1, Dipeptide-2, Dipropylene Glycol, Oryza Sativa (Rice) Extract, Pinus Densiflora Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Maltodextrin, Salvia Officinalis (Sage) Oil, Eucalyptus Globulus Leaf Oil, Juniperus Mexicana Oil, Butylene Glycol, Hydrolyzed Vegetable Protein, Hydrolyzed Gardenia Florida Extract, Gardenia Florida Fruit Extract, Dipotassium Glycyrrhizate, Centella Asiatica Extract, Hydrogenated Lecithin, Sodium Citrate, Polygonum Cuspidatum Root Extract, Scutellaria Baicalensis Root Extract, Propolis Extract, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Glycyrrhiza Glabra (Licorice) Root Extract, Leontopodium Alpinum Callus Culture Extract, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Citric Acid, Caprylyl Glycol, 1,2-Hexanediol, Calcium Chloride, Gellan Gum, Ethylhexylglycerin, Hydroxyacetophenone, Xanthan Gum, Dextrin

Package Label

Drug Facts	
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Extract, Chamomilla Recutita (Matricaria) Flower Extract, Eucalyptus Globulus Leaf Oil, Maltodextrin, Salvia Officinalis (Sage) Oil, Juniperus Mexicana Oil, Butylene Glycol, Hydrolyzed Vegetable Protein, Hydrolyzed Gardenia Florida Extract, Gardenia Florida Fruit Extract, Dipotassium Glycyrrhizate, Centella Asiatica Extract, Hydrogenated Lecithin, Sodium Citrate, Polygonum Cuspidatum Root Extract, Scutellaria Baicalensis Root Extract, Propolis Extract, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Glycyrrhiza Glabra (Licorice) Root Extract, Leontopodium Alpinum Callus Culture Extract, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Citric Acid, Caprylyl Glycol, 1,2-Hexanediol, Calcium Chloride, Gellan Gum, Ethylhexylglycerin, Hydroxyacetophenone, Xanthan Gum, Dextrin

REPUERA DERMATOZYME 5% HYDRO ESSENTIAL AMPULE

allantoin, glycerin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81459-303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	15 mg in 100 mL
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.01 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYANOCOBALAMIN (UNII: P6YC3EG204)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
DIPHENYL DIMETHICONE (100 CST) (UNII: AG1ANB6B8O)	
CHAMOMILE (UNII: FGL3685T2X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GARDENIA JASMINOIDES FRUIT (UNII: 7CTH8MD549)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
JUNIPERUS DEPPEANA WOOD OIL (UNII: 4739QA5686)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PREZATIDE COPPER (UNII: 6BJQ43T1I9)	
VALYLTRYPTOPHAN (UNII: 3G64B4AFQN)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PINUS DENSIFLORA LEAF (UNII: Q1Q9P50WY)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SAGE OIL (UNII: U27K0H1H2O)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
CERAMIDE NP (UNII: 4370DF050B)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PREZATIDE (UNII: 39TG2H631E)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
RICE GERM (UNII: 7N2B70SFEZ)	
ROSEMARY (UNII: IJ67X351P9)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81459-303-01	50 mL in 1 AMPULE; Type 0: Not a Combination Product	01/28/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/28/2021	

Labeler - ALLUV (695097760)

Registrant - ALLUV (695097760)

Establishment

Name	Address	ID/FEI	Business Operations
ALLUV		695097760	manufacture(81459-303)

Revised: 1/2021

ALLUV