

**REPUERA DERMATOZYME 5% ULTRA MOISTURE CREAM- glycerin,  
allantoin cream  
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.*

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**81459-302 re'puera DermAtozyme 5% Ultra Moisture Cream**

**Active Ingridients**

Glycerin (10%)

Allantoin (0.001%)

**Purpose**

Skin Protectant

**Uses**

pH 5.8 Less-Acid cream. Maintains healthy and smooth skin by providing sufficient nourishment from the inside of the skin.

**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 the cream to affected area and massage gently into the skin.

## Other Information

STORE AT ROOM TEMPERATURE

## Inactive Ingredients

Water, Eucalyptus Globulus Leaf Oil, Dipropylene Glycol, Caprylic/Capric Triglyceride, Polyglyceryl-3 Methylglucose Distearate, Cetearyl Alcohol, Limnanthes Alba (Meadowfoam) Seed Oil, Hydrogenated Poly(C6-14 Olefin), Hydrogenated Polydecene, Glyceryl Stearate, Dendropanax Morbiferus Extract, Cetearyl Oliviate, Sorbitan Oliviate, Behenyl Alcohol, Butylene Glycol, Oryza Sativa (Rice) Extract, Pinus Densiflora Leaf Extract, Cyanocobalamin, Copper Tripeptide-1, Ceramide NP, Hydrogenated Lecithin, Hydrolyzed Vegetable Protein, Maltodextrin, Centella Asiatica Extract, Sodium Citrate, Polygonum Cuspidatum Root Extract, Scutellaria Baicalensis Root Extract, Propolis Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Camellia Sinensis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Simethicone, Butyrospermum Parkii (Shea) Butter, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Caprylyl Glycol, Carbomer, Polyisobutene, Tromethamine, Xanthan Gum, Dextrin, Salvia Officinalis (Sage) Oil, Sorbitan Oleate, Caprylyl/Capryl Glucoside, Juniperus Mexicana Oil, Hydrolyzed Gardenia Florida Extract, Gardenia Florida Fruit Extract, Dipotassium Glycyrrhizate, Citric Acid, 1,2-Hexanediol, Ethylhexylglycerin, Hydroxyacetophenone, Disodium EDTA

## Package Label

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Glycerin (10%).....	Skin Protectant
Allantoin (0.001%).....	Skin Protectant
<b>Uses</b> ■ pH 5.8 Less-Acid cream. Maintains healthy and smooth skin by providing sufficient nourishment from the inside of the skin.	
<b>Warnings</b> For external use only	
Keep away from heat	

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glycerin, allantoin cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81459-302
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.001 mg in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	10 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>RICE GERM</b> (UNII: 7N2B70SFEZ)	
<b>PINUS DENSIFLORA LEAF</b> (UNII: Q1Q9P50WY)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SAGE OIL</b> (UNII: U27K0H1H2O)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HYDROGENATED POLY(C6-14 OLEFIN; 2 CST)</b> (UNII: POTX083987)	
<b>HYDROGENATED POLYDECENE (1500 CST)</b> (UNII: 4YI0729529)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>ICODEXTRIN</b> (UNII: 2NX48Z0A9G)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE</b> (UNII: W19EIO0DBE)	
<b>SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW)</b> (UNII: 1DXE3F3OZX)	
<b>JUNIPERUS DEPPEANA WOOD OIL</b> (UNII: 4739QA5686)	
<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>CAPRYLYL/CAPRYL OLIGOGLUCOSIDE</b> (UNII: E00JL9G9K0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	

<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)
<b>GARDENIA JASMINOIDES FRUIT</b> (UNII: 7CTH8MD549)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204)
<b>PREZATIDE COPPER</b> (UNII: 6BJQ43T1I9)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)
<b>POLYGONUM CUSPIDATUM ROOT</b> (UNII: 7TRV45YZF7)
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81459-302-01	80 mL in 1 TUBE; 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(81459-302)