

SNOW WHITE AMPOULE- allantoin cream
MICELL KOREA 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

Allantoin (0.01%) - Skin Protectact
Pyridoxine HCl (0.001%) - Skin Protectact

INACTIVE INGREDIENT

Water, Butylene Glycol, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Niacinamide, Polyglutamic acid, Methionine, Serine, Histidine, 1,2-Hexandiol, Hydroxyethylethylcellulose, Propylene Glycol, Calcium Pantothenate, Sodium Ascorbyl Phosphate, Tocopheryl Acetate, Maltodextrin / Sodium Starch Octenylsuccinate, Camellia Sinensis Leaf Extract, Citrus Aurantium Bergamia (Bergamot) Leaf Extract, Lavendula Angustifolia (Lavender) Flower Extract, Rosa Centifolia Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Alcohol, Centella Asiatica Extract, Polygonum Cuspidatum Root Extract, Scutellaria Baicalensis Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Chamomilla Recutita (matricaria) Flower Extract, Portulaca Oleracea Extract, Belamcanda Chinensis Root Extract, Betaine, Octanediol, Citrus grandis (grapefruit) seed extract, Artemisia princeps extract, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Xanthan Gum, Dipotassium Glycyrrhizate, Ethylhexylglycerin, Citric Acid, Disodium EDTA

PURPOSE

Skin Protectact

WARNINGS

For skin use only.

Do not use

☐ on puncture wounds ☐ on animal bites ☐ on serious burns ☐ on area with scratches, eczema, or dermatitis

When using this product

☐ avoid contact with eyes

Stop use and ask a doctor if

☐ you have allergy or skin disease

☐ rash or irritation develops and lasts

☐ red spots, swelling, itching, irritation and other abnormalities develops

KEEP OUT OF REACH OF CHILDREN SECTION

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

INDICATIONS & USAGE SECTION

☐ Clean skin thoroughly before using

☐ After cleansing, apply toner and press lightly. Then, apply a moisturizing cream

☐ Use it every days in the evening according to skin condition

DOSAGE & ADMINISTRATION SECTION

- Clean skin thoroughly before using
- After cleansing, apply toner and press lightly. Then, apply a moisturizing cream
- Use it every days in the evening according to skin condition

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



allantoin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71327-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	Allantoin	0.000004 g in 40 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68 Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	0.0000004 g in 40 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Methionine (UNII: AE28F7PNPL)	
Serine (UNII: 452VLY9402)	
Histidine (UNII: 4QD397987E)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Maltodextrin (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71327-007-01	40 mL in 1 PACKAGE; Type 0: Not a Combination Product	03/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/20/2017	

Labeler - MICELL KOREA CO.,LTD (689851542)

Registrant - MICELL KOREA CO.,LTD (689851542)

Establishment

Name	Address	ID/FEI	Business Operations
MICELL KOREA CO.,LTD		689851542	manufacture(71327-007)