

LEADERS MEDIU SOOTHING ALOE PACK- allantoin gel
SANSUNG LIFE & SCIENCE CO., LTD.

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.

ACTIVE INGREDIENT

Active Ingredient: Allantoin 0.50%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Glycerin, 1,2-Hexanediol, Butylene Glycol, Arginine, Carbomer, PEG-60 Hydrogenated Castor Oil, Aloe barbadensis Leaf Juice Powder, Sodium Polyacrylate, Portulaca Oleracea extract, Cucumis Sativus (Cucumber) Fruit extract, Fragrance, Buteth-3, Glyceryl Acrylate/Acrylic Acid Copolymer, Maltodextrin, PVM/MA Copolymer, Disodium EDTA, Sodium Benzotriazolyl Butylphenol Sulfonate, Tributyl Citrate, CI 19140, CI 42090, Sodium Hyaluronate

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: For external use only. Avoid contact with eyes. Not for human consumption. Discontinue use if irritation occurs. If irritation persists, consult a physician.

Use immediately after opening. Store in cool and dry place. Keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN

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Directions

Directions: After cleansing face, apply a thin layer of the Wash-Off Pack on the face, leaving out the area around eyes and mouth. Leave on for 5-10 minutes then wash off with tepid water. *Suggested use is 2-3 times a week

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LEADERS MEDIU SOOTHING ALOE PACK

allantoin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69424-530
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	Allantoin	50 mg in 10 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:69424-530-01	10 mL in 1 CELLO PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/01/2015	

Labeler - SANSUNG LIFE & SCIENCE CO., LTD. (689524929)**Registrant** - SANSUNG LIFE & SCIENCE CO., LTD. (689524929)**Establishment**

Name	Address	ID/FEI	Business Operations
SANSUNG LIFE & SCIENCE CO., LTD.		689524929	manufacture(69424-530)

Revised: 2/2016

SANSUNG LIFE & SCIENCE CO., LTD.