VASHTI- allantoin cream
LEADER GREEN 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 0.5%

INACTIVE INGREDIENT

Inactive ingredients: PONCIRUS TRIFOLIATA FRUIT, NARINGINASE, LOBELIA SPICATA LEAF, MINERAL OIL, VITAMINE C

Purpose

Purpose: Skin Protectant

WARNINGS

Warnings:
1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist.
1) In case of having problems such as red rash, swollenness, itching, stimulation during usage.
2) In case of having the same symptoms above on the part you put this product on by direct sunlight.
2. You are banned to use it on the part where you have a scar, eczema, or dermatitis.
3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:
Keep out of reach of babies and children

Indications and usage

Indications and usage:
After basic skin care, apply adequate amount following the skin texture and gently tap to enhance absorption.

Dosage and administration

Dosage and administration:
Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

VASHTI

allantoin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61221-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	Allantoin	0.25 mg in 50 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LOBELIA SPICATA LEAF (UNII: 1G4GK01F67)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61221-020-01	50 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/01/2013	

Labeler - LEADER GREEN CO., LTD. (688735493)

Registrant - LEADER GREEN CO., LTD. (688735493)

Establishment

Name	Address	ID/FEI	Business Operations
LEADER GREEN CO., LTD.		688735493	manufacture(61221-020)

Revised: 8/2013 LEADER GREEN CO., LTD.