## BL VITAL - allantoin cream RECELL U KOREA

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.

-----

#### **Drug Facts**

allantoin

water, butylene glycol, etc.

skin protectant

keep out of reach of the children

apply proper amount to the skin

- 1. Do not use in the following cases(Eczema and scalp wounds)
- 2.Side Effects
- 1)Due to the use of this druf if rash, irritation, itching and symptopms of hypersnesitivity occur dicontinue use and consult your phamacisr or doctor
- 3.General Precautions
- 1)If in contact with the eyes, wash out thoroughty with water If the symptoms are servere, seek medical advice immediately
- 2)This product is for exeternal use only. Do not use for internal use
- 4. Storage and handling precautions
- 1)If possible, avoid direct sunlight and store in cool and area of low humidity
- 2)In order to maintain the quality of the product and avoid misuse
- 3) Avoid placing the product near fire and store out in reach of children

for external use only



# BL Vital Cream

#### **BL VITAL**

allantoin cream

P I VUUCL IIIIVI IIIauvi	Prod	Informatio	n
--------------------------	------	------------	---

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:70047-0001

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z)	ALLANTOIN	0.1 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			

Packaging					
l	# Item Code Package Description		Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1	NDC:70047-0001-1	50 mL in 1 BOTTLE; 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	08/31/2015		

## Labeler - RECELL U KOREA (689515043)

### Registrant - RECELL U KOREA (689515043)

Establishment				
Name	Address	ID/FEI	Business Operations	
RECELL U KOREA		689515043	manufacture(70047-0001)	

Revised: 8/2015 RECELL U KOREA