ATOBOS- allantoin lotion
1004LABORATORY

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: Centella Asiatica Extract, Butylene Glycol, Glycerin, Caprylic/Capric Triglyceride, Butylene glycol Dicaprylate/Dicaprate, Cetyl Alcohol, Squalane, Stearyl Alcohol, Trehalose, Betaine, Panthenol, Glycosyl Trehalose, Hydrogenated Starch Hydrolysate, Dipotassium Glycyrrhizate, Cetearyl Olivate, Sorbitan Olivate, Sorbitan Stearate, Glyceryl Citrate/Lactate/Linoleate/Oleate, Beeswax, Butyrospermum Parkii (Shea) Butter, Macadamia Integrifolia Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Ceramide 3, Arginine, Ammonium Acryloyldimethy/VP Copolymer, Carbomer, Caprylyl Glycol, Caprylhydroxamic Acid, Citrus Aurantium Dulcis (Orange) Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Limon (Lemon) Peel Oil, Pelargonium Graveolens Flower Oil, Lavandula Hybrida Oil, Santalum Album (Sandalwood) Oil, Beta-Glucan, Portulaca Oleracea Extract, Sodium Hyaluronate, Water, Madecassoside, Asiaticoside, Madecassic Acid, Asiatic Acid

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: 1. Stop using the product if the following problems arise while using the product as continued use could worsen the symptoms; consult with a dermatologist. A. If red spots, swelling, itchiness, and irritation occur. B. If the above problems occur on the applied area on the skin from direct sunlight 2. Do not use on areas with wounds, eczema, and dermatitis. 3. Storage and handling precautions. A. Close the lid after use. B. Do not store in high- temperature or low- temperature and keep away from direct sunlight. 4. Wash off the product if it gets in the eye.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications & Usage: After washing the face & body, dispense an appropriate amount into your palm, and evenly apply to the entire face and body.

DOSAGE & ADMINISTRATION

Dosage & Administration: Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ATOBOS

allantoin lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69739-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	Allantoin	0.8 mg in 160 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Butylene Glycol (UNII: 3XUS85K0RA)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69739-030-01	160 mL in 1 CARTON; 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	03/01/2015	

Labeler - 1004LABORATORY (689512629)

Registrant - 1004LABORATORY (689512629)

Establishment

Name	Address	ID/FEI	Business Operations
1004LABORATORY		689512629	manufacture(69739-030)

Revised: 4/2015 1004LABORATORY