

LASTING RESULTS MOISTURIZER - octocrylene, octinoxate, oxybenzone, octisalate, avobenzone lotion
Biopelle, Inc.

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.

Lasting Results Moisturizer Broad Spectrum SPF 50

Active Ingredients

Octocrylene 10%

Octinoxate 7.5%

Oxybenzone 5%

Octisalate 5%

Avobenzone 3%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes.

Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of each of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply to face and under throat after cleansing
- reapply:
 - ◦ after excessive perspiration
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures including:
 - ◦ limit time in the sun, especially from 10 a.m. - 2 p.m.
 - ◦ wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

water, butyloctyl salicylate, aloe barbadensis leaf juice, propylene glycol, glyceryl stearate, peg-100 stearate, hexyldecanol, stearic acid, allantoin, phenoxyethanol, magnesium ascorbyl phosphate, cetyl alcohol, panthenol, acrylates/C10-30 alkyl acrylate crosspolymer, dimethicone, triethanolamine, caprylyl glycol, chlorphenesin.

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free - 1-866-424-6735 (weekdays)

Package Label

Principal Display

PHYSICIAN STRENGTH FORMULAE,
WITH CLINICALLY TESTED INGREDIENTS
THAT HELP THE APPEARANCE OF SKIN
AFTER AESTHETIC MEDICAL PROCEDURES.

PRESCRIBEDsolutions®
[CUSTOMIZED SKINCARE]

CUSTOMIZED TO GIVE YOU MORE
SKIN FIRING, MORE ANTI-OXIDANTS,
MORE MOISTURIZATION AND MORE
PERSONALIZED SKINCARE RESULTS.



Drug Facts	
Active Ingredients	Purpose
Octocrylene 10% Octinoxate 7.5% Oxybenzone 5% Octisalate 5% Avobenzone 3%	Sunscreen
Uses	
• helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun	

PRESCRIBEDsolutions is DISTRIBUTED BY BIOPELLE, INC.,
A FERNDALE PHARMA GROUP COMPANY, FERNDALE, MI 48220.
MADE IN USA/FABRIQUE AUX E.-U. B110055 r1

Broad Spectrum SPF 50
Lasting Results™ Moisturizer
Crème Hydratante SPF 50
75 ml e 2.5 fl oz

Peel Here
For Drug Facts →

Peel Label

Drug Facts (continued)

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes.
Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply to face and under throat after cleansing
- reapply:
 - after excessive perspiration
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats and sunglasses
 - children under 6 months: Ask a doctor

Drug Facts (continued)

Inactive ingredients

water, butyloctyl salicylate, aloe barbadensis leaf juice, propylene glycol, glyceryl stearate, peg-100 stearate, hexyldecanol, stearic acid, allantoin, phenoxyethanol, magnesium ascorbyl phosphate, cetyl alcohol, panthenol, acrylates/C10-30 alkyl acrylate crosspolymer, dimethicone, triethanolamine, caprylyl glycol, chlorphenesin.

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free - 1-866-424-6735 (weekdays)

LASTING RESULTS MOISTURIZER

octocrylene, octinoxate, oxybenzone, octisalate, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42485-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HEXYLDECANOL (UNII: 151Z7P1317)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PANTHENOL (UNII: WV9CM0O67Z)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42485-007-01	75 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/01/2012	

Labeler - Biopelle, Inc. (808158823)

Registrant - Biopelle, Inc. (808158823)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, LLC		172198223	manufacture

Revised: 5/2012

Biopelle, Inc.