# ABSOLUE PREMIUM BX SUNSCREEN BROAD SPECTRUM SPF 15 ABSOLUTE REPLENISHING- avobenzone, octisalate, octocrylene cream BPS 60

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.

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#### Absolue Premium Bx Sunscreen Broad Spectrum SPF 15 Absolute Replenishing Lotion

#### **Drug Facts**

#### Active ingredients

Avobenzone 3%

Octisalate 3%

Octocrylene 8%

#### **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 reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

For sunscreen use:

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 value of 15 or higher and other sun protection measures including:

- limit time in the sun. especially from 10 a.m. 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: Ask a doctor

#### Other information

• protect the product in this container from excessive heat and direct sun

#### **Inactive ingredients**

water, glycerin, cyclohexasiloxane, alcohol denat., caprylic/capric triglyceride, PEG-20 methyl glucose sesquistearate, C12-15 alkyl benzoate, tocopheryl acetate, C13-14 isoparaffin, hydroxypropyl tetrahydropyrantriol, hydrolyzed malt extract, padina pavonica extract, hydrolyzed soy protein, stearic acid, adenosine, triethanolamine, polyacrylamide, calcium pantothenate, dimethyl isosorbide, limonene, xanthan gum, linalool, dioscorea villosa (wild yam) root extract, iron oxides, caprylyl glycol, capryloyl salicylic acid, paraffin, disodium EDTA, butylene glycol, cetyl alcohol, octyldodecanol, citronellol, laureth-7, hexyldecanol, fragrance

#### Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)

#### **Package Labeling:**

Absolute Replenishing Lotion Repair - Intense Moisture - Clarity Broad Spectrum SPF 15 From Lancôme Laboratories comes Absolue Premium 8x, an age-targeted skincare which visibly replenishes, repairs and rejuvenates skin.

Age and hormonal changes are known to weaken skin at the structural level, leaving it dry, less elastic and dull.

Patented Lancôme innovation: Pro-Xylane™ helps restore essential moisture deep in skin's surface, plumping it to help skin restore density, firmness and radiance - as if signs of aging are visibly repaired.

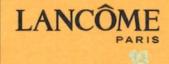
The replenishing ßio-Network™ of Wild Yam, Soy, Sea Algae and Barley helps complete the visible

The transformation

Immediately skin feels intensely moisturized. See fine lines and wrinides visibly reduced. Feel renewed firmness and elasticity. See revived clarity and even

Skin recovers the supple fullness of youthful looking skin. It is visibly rejuvenated, as if full of life.

Oil-free Non-comedogenic Non-acnegenic Dermatologist-tested for safety



#### **Drug Facts**

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 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

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

#### **Directions**

For sunscreen use:

- apply generously and evenly 15 minutes before sun exposure reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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 value of 15 or higher and other
- sun protection measures including:
  limit time in the sun, especially from
- 10 a.m. 2 p.m.

  wear long-sleeved shirts, pants, hats, and sunglasses

  children under 6 months of age: Ask a

#### Other information

· protect the product in this container from excessive heat and direct sun

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#### laureth-7, hexyldecanol, fragrance Questions or comments?

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THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS LANCOME - PARIS 29, rue du Faubourg St Honoré

LANCÔME, LUXURY PRODUCTS LLC, NEW YORK, NY 10017 IMP. BY LANCÔME CANADA MONTRÉAL, H4T 1K5 TSA 10007 F 92667 ASNIERES CEDEX







**ABSOLUE** 

PREMIUM Bx

SUNSCREEN

**BROAD SPECTRUM SPF 15** ABSOLUTE REPLENISHING LOTION

€75 ml NET WT 2.5 FL. OZ.

### ABSOLUE PREMIUM BX SUNSCREEN BROAD SPECTRUM SPF 15 ABSOLUTE REPLENISHING

avobenzone, octisalate, octocrylene cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70581-003

Route of Administration TOPICAL, TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ALCOHOL (UNII: 3K9958V90M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PEG-20 METHYL GLUCO SE SESQUISTEARATE (UNII: 0345752X7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HYDROXYPROPYL TETRAHYDROPYRANTRIOL (UNII: 4U3GMG1OT1)	
PADINA PAVONICA (UNII: 177U06NHZI)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ADENO SINE (UNII: K72T3FS567)	
TROLAMINE (UNII: 9O3K93S3TK)	
CALCIUM PANTO THENATE (UNII: 568 ET80 C3D)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
DIO SCOREA VILLO SA TUBER (UNII: IWY3IWX2G8)	
FERRIC O XIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)	
CAPRYLO YL SALICYLIC ACID (UNII: 5F7PJF6 AA4)	
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E )	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OCTYLDO DECANO L (UNII: 46 1N1O 6 14 Y)	
LAURETH-7 (UNII: Z95S6G8201)	

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:70581-003-75	1 in 1 BOX	04/09/2016		
1		75 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 not final	part352	04/09/2016	

## **Labeler** - BPS 60 (272259304)

Establishment				
Name	Address	ID/FEI	Business Operations	
BPS 60		272259304	pack(70581-003)	

Revised: 12/2019 BPS 60