

BOTANICS TRIPLE AGE RENEWAL DAY ALL BRIGHT SUNSCREEN BROAD SPECTRUM SPF 15- avobenzone, octisalate, octocrylene cream
BCM 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.

Carton Active Ingredients Section

Active Ingredients

Avobenzone 3%

Octisalate 3%

Octocrylene 5%

Purpose Sunscreen

Uses

Uses - helps prevent sunburn.

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

Ask a doctor

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

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

Directions

Directions for sunscreen use

apply liberally 15 minutes before sun exposure

reapply at least every 2 hours

use a water resistant sunscreen if swimming or sweating

children under 6 months of age: Ask a doctor

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

Storage

Other information - protect the product in this container from excessive heat and direct sun

Inactive ingredients

Aqua (Water), C12-15 alkyl benzoate, Glycerin, Dimethicone, Cetearyl glucoside, Prunus amygdalus dulcis (Sweet almond) oil, Tribehenin, Astrocaryum murumuru butter, Butyrospermum parkii (Shea) butter, Sodium polyacrylate, Cetearyl alcohol, Potassium cetyl phosphate, Phenoxyethanol, Dimethicone crosspolymer, Caprylyl glycol, Ascorbyl glucoside, Citric acid, Xanthan gum, Parfum (Fragrance), Sodium benzoate, Hydrolyzed hyaluronic acid, Tocopheryl acetate, Retinyl palmitate, Ethylhexylglycerin, Orchis mascula extract, Tetrasodium EDTA, Dipropylene glycol, Glycine soja (soyabean) protein, Citronellol, Silica, Tocopherol

Description

Firms, lifts and reduces the appearance of deep lines and wrinkles.

Active plant extract, Purple Orchid contains anti-oxidants and polysaccharides to help protect and smooth the skin.

Directions: Use every morning after cleansing. Colour may vary due to natural ingredients. Formulated without parabens.

Information

Made in the UK.

The Boots Company PLC Nottingham England NG2 3AA

Dist. in the USA by Boots Retain USA Inc. Norwalk CT 06851 USA

www.boots.com

Jar label

Boots Botanics The Power of Plants

Day Cream Sunscreen Broad Spectrum SPF 15

50ml e 1.69 US Fl. Oz.

Active ingredients: Avobenzone 3%, Octisalate 3%, Octocrylene 5%

Warnings

Avoid contact with eyes. If product gets into the eyes, rinse well with water immediately.

Description

Directions: Use every morning after cleansing

Information

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avobenzone, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11489-084
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.5 g in 50 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ALMOND OIL (UNII: 66YXD4DKO9)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ORCHIS MASCULA WHOLE (UNII: 4119KOT30J)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11489-084-01	1 in 1 CARTON		
1		50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/14/2013	

Labeler - BCM Ltd (230780322)

Registrant - The Boots Company Plc (218622660)

Establishment

Name	Address	ID/FEI	Business Operations
BCMLtd		230780322	manufacture(11489-084) , analysis(11489-084)

Revised: 12/2012

BCM Ltd