

BOTANICS TRIPLE ACTION DAY MOISTURE SUNSCREEN SPF 15 - octinoxate and avobenzone 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 and jar labelling

BOTANICS TRIPLE ACTION DAY MOISTURE CREAM SUNSCREEN SPF 15

Active Ingredients Purpose

Avobenzone 3.0% Sunscreens

Octinoxate 4.5%

Uses

- Provides moderate protection against the adverse effects of the sun
- Higher SPF gives more protection

Warnings

For external use only

When using this product keep out of eyes. If contact occurs rinse thoroughly with cold water. Avoid direct contact with fabric.

Colour may vary due to natural extracts

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help.

DIRECTIONS

- Massage onto face and neck with gentle upward strokes.
- Apply evenly at least 15 minutes before sun exposure.
- Reapply as required.
- Not intended for children under the age of 12.
- Not intended for protection while sunbathing.

Other Information

Do not store above 30⁰C or 86⁰F

Inactive Ingredients

Aqua (Water), C12-15 alkyl benzoate, Butylene glycol, Dimethicone, Polyglyceryl-3 methylglucose distearate, C18-36 acid glycol ester, Butyrospermum parkii (Shea butter), Aesculus hippocastanum (Horsechestnut) extract, Theobroma cacao (Cocoa) seed butter, Phenoxyethanol, VP/hexadecene copolymer, Sodium benzoate, Parfum (Fragrance), Methylparaben, Acrylates/vinyl isodecanoate crosspolymer, Tetrasodium EDTA, Butylparaben, Ethylparaben, Potassium hydroxide, Maltodextrin, Propylparaben, Isobutylparaben, Dipropylene glycol, Silica, BHT

Questions? 1-866-75-BOOTS

Plant extracts at levels that really work, combined and formulated for outstanding product performance. Naturally.

A triple action formulation for a complete daily skincare routine: moisturises, protects and promotes

healthy looking skin. Horsechestnut extract a powerful anti-oxidant and SPF15 help protect against premature skin ageing.

Dermatologically tested.

Mfd in the U.K. for BBI NG2 3AA. UK.

Dist in the USA by Boots Retail USA Inc.

Stamford CT 06901

www.boots.com

Carton label

Normal/Dry Skin

Triple Action Day Moisture Cream Sunscreen SPF 15

PEAU NORMALE ET SECHE

Crème Hydratante de Jour à Triple Action FPS 15

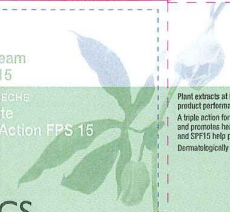

Boots

The Power of Plants

BOTANICS

50ml e 1.69 US Fl. Oz

TA Day Moisture Cream carton.jpg

Drug Facts Active Ingredients Avobenzone 3.0% Octinoxate 4.5% Purpose Sunscreens	Drug Facts (continued) DIRECTIONS • Massage onto face and neck with gentle upward strokes. • Apply evenly at least 15 minutes before sun exposure. • Reapply as required. • Not intended for protection while sunbathing. Other Information Do not store above 30°C or 86°F Inactive Ingredients Aqua (Water), C12-15 alkyl benzoate, Butylene glycol, Dimethicone, Polyphenyl-3 methylglucoside distearate, C18-36 acid glycol ester, Butyrpernum parkii (Shea butter), Aesculus hippocastanum (horse chestnut) extract, Theobroma cacao (Cocoa) seed butter, Phenoxyethanol, VP/hexadecene copolymer, Sodium benzoate, Parfum (Fragrance), Methylparaben, Acrylates/Vinyl isocacanoate crosspolymer, Tetrasodium EDTA, Butylparaben, Ethylparaben, Potassium hydroxide, Maltodextrin, Propylparaben, Isobutylparaben, Dipropylene glycol, Silica, BHT Questions? 1-866-75-BOOTS	NORMAL/DRY SKIN Triple Action Day Moisture Cream Sunscreen SPF 15 PEAU NORMALE ET SECHE Crème Hydratante de Jour à Triple Action FPS 15  The Power of Plants BOTANICS 50 ml e 1.69 US Fl. Oz.	 Plant extracts at levels that really work, combined and formulated for outstanding product performance. Naturally. A triple action formulation for a complete daily skincare routine: moisturizes, protects and promotes healthy looking skin. Horsechestnut extract a powerful anti-oxidant and SPF15 help protect against premature skin ageing. Dermatologically tested. Mfd in the U.K. for BBI NG2 3AA. UK. Dist in the USA by Boots Retail USA Inc. Stamford CT 06901 www.boots.com
--	--	---	--

Jar front label

Triple Action Day Moisture Cream Sunscreen SPF 15

Horsechestnut protects

Crème Solaire Hydratante de Jour à Triple Action FPS 15

Le Marronnier d'Inde protège

Boots

The Power of Plants

BOTANICS

50ml e 1.69 US Fl. Oz

TA Day Moisture Cream front label.jpg



Jar back label

Dermatologically tested

WARNINGS: Avoid getting directly in eyes. If contact occurs rinse thoroughly with cold water. Avoid direct contact with fabric. Colour may vary due to natural extracts.

Dermo-teste

MISE EN GARDE: Éviter tout contact avec les yeux. En cas de projection, rincer immédiatement à l'eau froide. Éviter tout contact direct avec du tissu. La couleur peut varier en raison des extraits naturels.

ACTIVE INGREDIENTS/ACTIFS: Avobenzon 3.0% Octinoxate 4.5%

Mdf in the U.K. for/Fabriqué au R.-U. pour BBI NG2 3AA. UK.

Dist in the USA by/aux É.-U. par Boots Retail USA Inc. Stamford CT 06901

USA/Canada: Questions? 1-866-75-BOOTS

www.boots.com

TA Day Moisture Cream back label.jpg



BOTANICS TRIPLE ACTION DAY MOISTURE SUNSCREEN SPF 15
 octinoxate and avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11489-066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 mL in 50 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 mL in 50 mL	

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
COCOA BUTTER (UNII: 512OYT1CRR)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
BUTYL PARABEN (UNII: 3QPII U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11489-066-01	1 in 1 CARTON		
1		50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/20/2010	

Labeler - BCM Ltd (230780322)

Registrant - The Boots Company PLC (218622660)

Establishment

Name	Address	ID/FEI	Business Operations
BCM Ltd		230780322	manufacture, analysis