

## **BOTANICS DAY MOISTURE SUNSCREEN SPF 12 - octinoxate, avobenzone and octisalate cream**

**Boots Retail USA 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.*

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### **carton and jar labelling**

BOTANICS DAY MOISTURE CREAM SUNSCREEN SPF 12

#### **Active Ingredients      Purpose**

Avobenzone 3%              Sunscreens  
Octinoxate 7.5%  
Octisalate 2.5%

#### **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.

Rinse with water to remove.

**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**

- Gently massage onto face and neck.
- 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 30°C or 86°F

#### **Inactive ingredients**

Aqua (Water), Glycerin, Butylene glycol, Caprylic/capric triglyceride, PPG-15 stearyl ether, Dimethicone, Steareth-21, Mel (Honey), Cetyl alcohol, Steareth-2, Polyacrylamide, Phenoxyethanol, C13-14 isoparaffin, Hydrolyzed rice bran protein, Methylparaben, Parfum (Fragrance), Sodium benzoate, Laureth-7, Propylparaben, Citric acid, Sodium chloride, Tetrasodium EDTA, Linalool, Benzyl salicylate, BHT, Sodium citrate, Hexyl cinnamal, Limonene, Hydroxycitronellal, Citronellol, Geraniol, Dipropylene glycol, Apha-isomethyl ionone, Ethylparaben, Butylparaben, Isobutylparaben, CI 19140 (Yellow 5).

#### **USA Questions?1-866-75-BOOTS**

**Plant extracts at levels that really work.**

This rich, indulgent cream instantly hydrates then continues to top up the skin's natural moisture level for up to 12 hours. With honey and rice extract to restore, plump and smooth your skin. With UVA/UVB

SPF12 protection to target skin ageing.

Dermatologically tested

Mfd in the UK for Boots Beauty International Limited

NG2 3AA. UK

Dist in the USA by Boots Retail USA Inc.

Stamford CT 06901

USA: Questions? 1-866-75-BOOTS

www.boots.com

**ACTIVE INGREDIENTS:** Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 2.5%.

**IN-ACTIVE INGREDIENTS:** Aqua (Water), Glycerin, Butylene glycol, Caprylic/capric triglyceride, PPG-15 stearyl ether, Dimethicone, Steareth-21, Mel (Honey), Cetyl alcohol, Steareth-2, Polyacrylamide, Phenoxyethanol, C13-14 isoparaffin, Hydrolyzed rice bran protein, Methylparaben, Parfum (Fragrance), Sodium benzoate, Laureth-7, Propylparaben, Citric acid, Sodium chloride, Tetrasodium EDTA, Linalool, Benzyl salicylate, BHT, Sodium citrate, Hexyl cinnamal, Limonene, Hydroxycitronellal, Citronellol, Geraniol, Dipropylene glycol, Alpha-isomethyl ionone, Ethylparaben, Butylparaben, Isobutylparaben, CI 19140 (Yellow 5).

Mfd in the UK for BBI Ltd NG2 3AA. UK Dist in the USA

by Boots Retail USA Inc. Stamford CT 06901

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Plant extracts at levels that really work.

This rich, indulgent cream instantly hydrates then continues to top up the skin's natural moisture level for up to 12 hours. With honey and rice extract to restore, plump and smooth your skin. With UVA/UVB SPF12 protection to target premature skin ageing.

Dermatologically tested.

Directions: Use daily, alone or under make up, following your cleansing routine. Massage onto skin using upward strokes.

Colour may vary due to natural extracts.

Warnings: Avoid contact with eyes. May cause irritation.

If contact occurs, rinse immediately with cold water.

If irritation persists, consult your physician immediately.

Avoid direct contact with fabric.

The Power of Plants

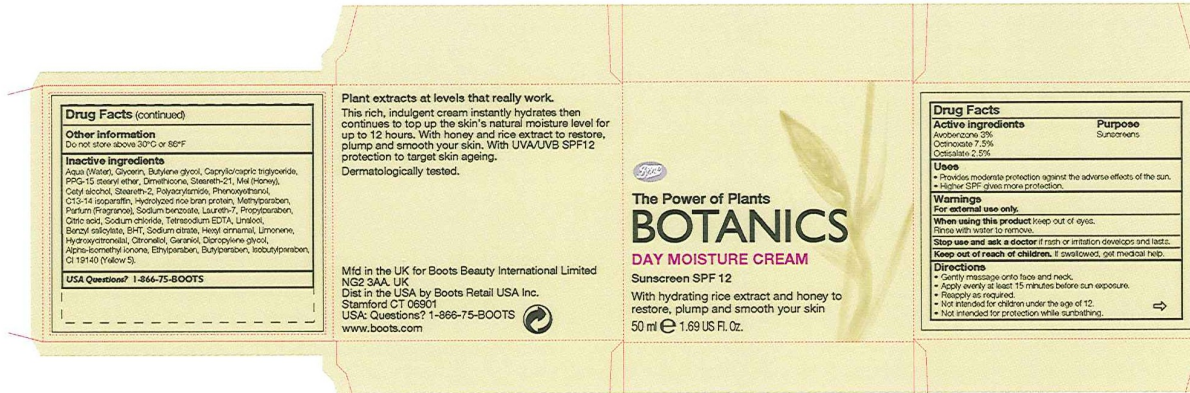
BOTANICS

DAY MOISTURE CREAM

Sunscreen SPF 12

With hydrating rice extract and honey to restore, plump and smooth your skin.

50ml e 1.69 US Fl. Oz.



The Power of Plants  
BOTANICS  
DAY MOISTURE CREAM  
Sunscreen SPF 12  
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**DAY MOISTURE CREAM**  
 Sunscreen SPF 12  
 With hydrating rice extract and honey.  
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**TOP**

**ACTIVE INGREDIENTS:** Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 2.5%.  
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Mfd in the UK for BBI Ltd NG2 3AA, UK Dist in the USA  
 by Boots Retail USA Inc, Stamford CT 06901  
 USA: Ousestone? 1-866-75-BOOTS www.boots.com **PENS2** 

**REVERSE**

**Plant extracts at levels that really work.**  
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 Dermatologically tested.  
**Directions:** Use daily, alone or under make up, following your cleansing routine. Massage onto skin using upward strokes.  
 Colour may vary due to natural extracts.

**BASE**

**Warnings:** Avoid contact with eyes. May cause irritation. If contact occurs, rinse immediately with cold water. If irritation persists, consult your physician immediately.  
 Avoid direct contact with fabric.

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**BOTANICS DAY MOISTURE SUNSCREEN SPF 12**

octinoxate, avobenzone and octisalate cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68472-074 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

|   |            |                  |
|---|------------|------------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 3.75 mL in 50 mL |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 1.5 mL in 50 mL  |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 1.25 mL in 50 mL |

### Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                      |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                   |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)            |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U) |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                |          |
| <b>HONEY</b> (UNII: Y9H1V576FH)                      |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)              |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)             |          |
| <b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)         |          |
| <b>RICE BRAN</b> (UNII: R60QEP13IC)                  |          |
| <b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)             |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)            |          |
| <b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)             |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)    |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)            |          |
| <b>EDETATE SODIUM</b> (UNII: MP1J8420LU)             |          |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)   |          |
| <b>ETHYL PARABEN</b> (UNII: 14255EXE39)              |          |
| <b>BUTYL PARABEN</b> (UNII: 3QPII03FV8)              |          |
| <b>ISOBUTYL PARABEN</b> (UNII: 0QQJ25X58G)           |          |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)      |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:68472-074-01 | 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                                  | 02/25/2010           |                    |

**Labeler** - Boots Retail USA Inc (143151533)

**Registrant** - The Boots Company PLC (218622660)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

