

**BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION
SUNSCREEN BROAD SPECTRUM SPF 15 DEEP BROWN NO.66- avobenzone, octinoxate,
octisalate cream
Burberry Limited**

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.

**Burberry Cashmere Long-Lasting Flawless Soft-Matte Foundation Sunscreen Broad Spectrum
SPF 15 Deep Brown No.66**

Drug Facts

Active ingredients

Avobenzone 3.0%

Octinoxate 3.5%

Octisalate 4%

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

- Apply liberally 15 mins before sun exposure.
- Reapply at least every 2 hrs.
- 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 doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, cyclopentasiloxane, isododecane, caprylyl methicone, butylene glycol, methyl trimethicone, PEG/PPG-18/18 dimethicone, diphenyl dimethicone/vinyl diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer, methyl methacrylate crosspolymer, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, PEG-10 dimethicone phenyl trimethicone, glycerin, sodium chloride, octyldodecanol, alcohol, acrylates/dimethicone copolymer, VP/VA copolymer, phenoxyethanol, disteardimonium hectorite, caprylyl glycol, tocopheryl acetate, triethoxycaprylylsilane, propylene carbonate, disodium EDTA, gum arabic tree (acacia senegal) gum, xanthan gum, sodium hyaluronate, dog rose (rosa canina) fruit extract, BHT, tea (camellia sinensis) leaf extract, citric acid, tocopherol, sodium benzoate, potassium sorbate, spanish lavender (lavandula stoechas) extract. May contain: Titanium dioxide, iron oxides, bismuth oxychloride.

Product Label





BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 DEEP BROWN NO.66

avobenzone, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69038-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	35 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TEA LEAF (UNII: GH42T47V24)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
ISODODECANE (UNII: A8289P68Y2)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALCOHOL (UNII: 3K9958V90M)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ACACIA (UNII: 5C5403N26O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69038-023-00	1 in 1 CARTON	06/23/2015	
1		30 mL in 1 PACKAGE; 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	06/23/2015	

Labeler - Burberry Limited (210047627)

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