BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 20 OCHRE NUDE NO.12- avobenzone, octinoxate, octis alate 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 20 Ochre Nude No.12

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 swiming 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

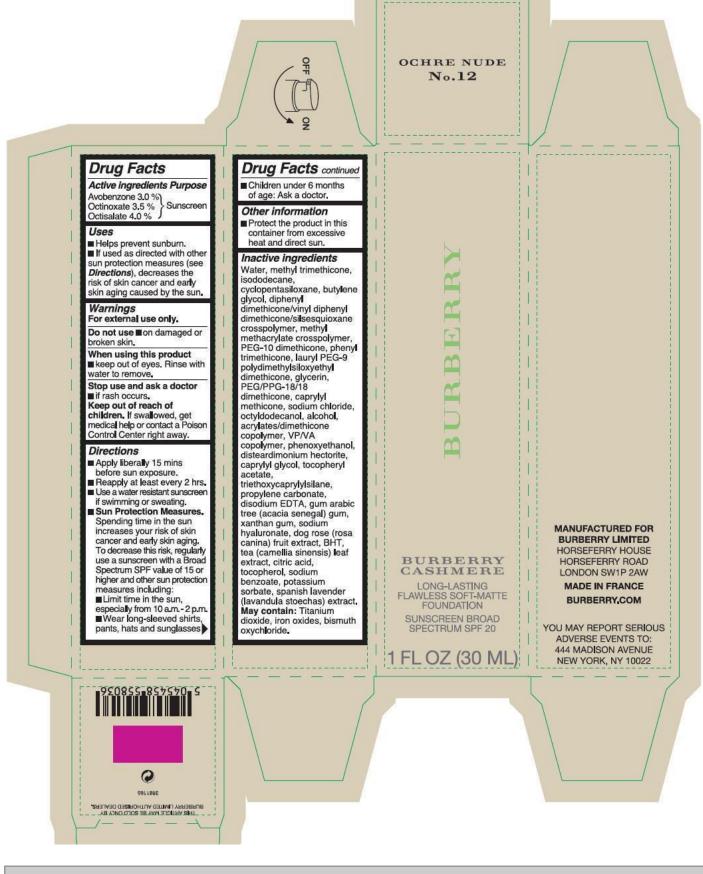
• Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, methyl trimethicone, isododecane, cyclopentasiloxane, butylene glycol, diphenyl dimethicone/vinyl diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane cross polymer, methyl methacrylate crosspolymer, PEG-10 dimethicone, phenyl trimethicone, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, glycerin, PEG/PPG-18/18 dimethicone, caprylyl methicone, 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 oxycholride.

Product Label





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avobenzone, octinoxate, octisalate cream

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69038-027			
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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	40 mg in 1 mL			

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
ISODODECANE (UNII: A8289P68Y2)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICO NE (UNII: 9 H0 AO 7T 79 4)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
O CTYLDO DECANO L (UNII: 46 1N1O6 14Y)	
ALCOHOL (UNII: 3K9958V90M)	
COPOVIDONE K25-31 (UNII: D9 C330 MD8 B)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
ACACIA (UNII: 5C5403N26O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
TEA LEAF (UNII: GH42T47V24)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC O XIDE RED (UNII: 1K09F3G675)	
BISMUTH O XYCHLO RIDE (UNII: 4ZR792I587)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69038-027-00	1 in 1 CARTON	06/23/2015			
1		30 mL in 1 PACKAGE; Type 0: Not a Combination Product				
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Marketing Information						
	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
O'	TC monograph not fin	al part352	06/23/2015			

Labeler - Burberry Limited (210047627)

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