DRUNK ELEPHANT UMBRE SHEER DEFENSE SPF-30- zinc oxide lotion Drunk Elephant, LLC

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.

DRUNK ELEPHANT™ UMBRA SHEER™ DEFENSE SPF-30

Drug Facts

Active ingredient

Zinc Oxide 20%

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 product is swallowed, get medical help or contact a Poison Control Center right away.

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
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging.

To decrease the 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other information

• protect this product from excessive heat and direct sun.

Inactive ingredients

water, caprylic/capric triglyceride, dicaprylyl carbonate, pentylene glycol, glycerin, steareth-2, propanediol, steareth-21, polyhydroxystearic acid, cetearyl alcohol, silica, sclerocarya birrea seed oil, aloe barbadensis leaf extract, chondrus crispus extract, haematococcus pluvialis extract, helianthus annuus (sunflower) sprout extract, vitis vinifera (grape) juice extract, helianthus annuus (sunflower) seed oil, simmondsia chinensis (jojoba) seed oil, raspberry seed oil/tocopheryl succinate aminopropanediol esters, hydrolyzed wheat protein, tocopheryl acetate, tocopherol, sea water, acetyl glucosamine, cetearyl glucoside, sodium stearoyl glutamate, tetrahexyldecyl ascorbate, glycine, sucrose, lecithin, triethoxycaprylylsilane, xanthan gum, trisodium ethylenediamine disuccinate, caprylhydroxamic acid, caprylyl glycol, phenoxyethanol, chlorphenesin, sodium dehydroacetate, iron oxides (CI 77491)

Questions or comments

• 800.604.1795

Dist. by: Drunk Elephant[®] Newport Beach, CA 92663, USA

PRINCIPAL DISPLAY PANEL - 90 ml Tube Box

EST<u>D</u> 2012

DRUNK ELEPHANT™

Umbra Sheer™ Physical Daily Defense

PROTECT + PRESERVE

SUNSCREEN BROAD SPECTRUM SPF 30

20% Zinc Oxide Sunflower Shoot Extract

90 ml / 3 fl oz





This sheer, physical sunscreen delivers UVA/UVB protection and is loaded with potent antioxidants like astaxanthin, grape juice and sunflower shoot extracts to minimize the appearance of photoaging for a more youthful-looking complexion. Infused with raspberry seed and marula oils, Umbra Sheer™ delivers essential moisture and minimizes the look of fine lines and wrinkles for skin that appears healthy and preserved. This unique formulation is ideal for daily use without any white residue or greasiness. Umbra Sheer™ is suitable for all skin, including the most sensitive.



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DRUNK ELEPHANT UMBRE SHEER DEFENSE SPF-30

zinc oxide lotion

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:69455-964

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 mg in 100 mL

Inactive Ingredients Ingredient Name Strength DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) GLYCERIN (UNII: PDC6A3C0OX) PENTYLENE GLYCOL (UNII: 50C1307PZG) STEARETH-2 (UNII: V56DFE46J5) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) STEARETH-21 (UNII: 53J3F32P58)

CODUM CILI ORIDE (LINII), 451W47IOOV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
WINE GRAPE JUICE (UNII: JHQ6158A7R)	
WHEAT (UNII: 4J2I0SN84Y)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCINE (UNII: TE7660XO1C)	
SUCROSE (UNII: C151H8M554)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
.ALPHATOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE)	
HAEMATOCOCCUS PLUVIALIS (UNII: 31T0FF0472)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69455-964- 15	1 in 1 BOX	12/13/2018		
1		90 mL in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH	nor+252	12/12/2010	

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Labeler - Drunk Elephant, LLC (057204632)

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