

**OHUI POWDERY METAL CUSHION COMPACT 01 LIGHT BEIGE- titanium dioxide powder
LG Household and Health Care 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.

ACTIVE INGREDIENTS

ENSULIZOLE 2.7%, OCTINOXATE 7%, TITANIUM DIOXIDE 7.18%, ZINC OXIDE 2.91%

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 the eyes. Rinse with water to remove.

Stop use and ask 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

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- **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. to 2 p.m.
- Wear longsleeved 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


CYCLOPENTASILOXANE, WATER, METHYL TRIMETHICONE, DIPROPYLENE GLYCOL, PEG-10 DIMETHICONE, POLYMETHYL METHACRYLATE, NIACINAMIDE, TROMETHAMINE, 1,2-HEXANEDIOL, DISTEARDIMONIUM HECTORITE, STEARIC ACID, ALUMINUM HYDROXIDE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, SODIUM CHLORIDE, SORBITAN SESQUIOLEATE, SORBITAN SESQUIISOSTEARATE, ZINC STEARATE, DISTEARYLDIMONIUM CHLORIDE, TOCOPHERYL ACETATE, PALMITOYL PROLINE, DIMETHICONE/METHICONE COPOLYMER, ADENOSINE, MAGNESIUM PALMITOYL GLUTAMATE, SODIUM PALMITOYL SARCOSINATE, PHENOXYETHANOL, TRIETHOXYCAPRYLYLSILANE, TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, BIOSACCHARIDE GUM-1, PALMITIC ACID, BUTYLENE GLYCOL, CETYL PEG/PPG-10/1 DIMETHICONE, HEXYL LAURATE, POLYGLYCERYL-4 ISOSTEARATE, ALBIZIA JULIBRISSIN BARK EXTRACT, FRAGRANCE, TITANIUM DIOXIDE(CI 77891), MICA, IRON OXIDES(CI 77492), IRON OXIDES(CI 77491), IRON OXIDES(CI 77499)

PRINCIPAL DISPLAY PANEL - 15 g Container 01 Light Beige

OHUI Powdery Metal Cushion Compact

Sunscreen Broad Spectrum SPF 50

Net Wt. 1.05 oz / 30 g (15gx2)

		<p>POWDERY METAL CUSHION COMPACT COUSSIN POUR LE TEINT MÉTAL Broad Spectrum SPF 50</p> <p>01 Light Beige Beige Clair</p>																																																			
<p>OHUI POWDERY METAL CUSHION COMPACT Broad Spectrum SPF 50</p> <p>This cushion foundation helps to keep a long-lasting coverage with liquid-to-powder formula, leaving skin flawless and silky smooth. How to Use: Place the puff on the metal plate and press down to pump once or twice. Tap gently to spread evenly over the face.</p> <p>Ce fond de teint en coussin promet une couverture de longue durée. Avec sa poudre liquide il laisse la peau douce et soyeuse. Utilisation: placez la houppette sur la plaque de métal et pompez une ou deux fois. Tapotez délicatement pour répartir sur le visage.</p> <p>Imported by LG Household & Health Care America, Inc. Santa Fe Springs, CA 90670 USA Questions: 1-888-498-9004 MADE IN KOREA</p>	<table border="1"> <tr> <td>Drug Fact (Continued)</td> </tr> <tr> <td>Other Information ■ Protect this product from excessive heat and direct sun.</td> </tr> <tr> <td>Inactive Ingredients Cyclopentasiloxane, Water, Methyl Trimethicone, Dipropylene Glycol, PEG-10 Dimethicone, Polymethyl Methacrylate, Niacinamide, Tromethamine, 1,2-Hexanediol, Distearidimonium Hectorite, Stearic Acid, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Sodium Chloride, Sorbitan Sesquioxide, Sorbitan Sesquiseostearate, Zinc Stearate, Distearylmonium Chloride, Tocopheryl Acetate, Palmitoyl Proline, Dimethicone/Methicone Copolymer, Adenosine, Magnesium Panthoyl Glutamate, Sodium Panthoyl Sarcosinate, Phenoxyethanol, Triethoxycaprylylsilane, Triethoxysilyl Polydimethylsilyloxyethyl Hexyl Dimethicone, Biosaccharide Gum-1, Palmitic Acid, Butylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Honey Laurate, Polyglyceryl-4 Isostearate, Albizia Julibrissin Bark Extract, Fragrance, Titanium dioxide(CI 77891), Mica, Iron Oxides(CI 77491, CI 77492, CI 77499)</td> </tr> <tr> <td>Questions? 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<p>H9790709</p> 																																																					

OHUI POWDERY METAL CUSHION COMPACT 01 LIGHT BEIGE

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53208-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.077 g in 15 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	0.405 g in 15 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.05 g in 15 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.436 g in 15 g

Inactive Ingredients

Ingredient Name	Strength
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOMETHICONE 5 (UNII: 0TH15PC10R)	
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
NIACINAMIDE (UNII: 25X51I8RD4)	
TROMETHAMINE (UNII: 023C2WHX2V)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53208-602-01	2 in 1 CARTON	01/25/2016	
1		15 g in 1 CONTAINER; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/25/2016	

Labeler - LG Household and Health Care Inc (688276187)

Establishment

Name	Address	ID/FEI	Business Operations
LG Household and Health Care Inc		688276187	manufacture(53208-602)

Establishment

Name	Address	ID/FEI	Business Operations
ZENISCE Co.Ltd.		690188305	manufacture(53208-602)

Revised: 2/2016

LG Household and Health Care Inc