

O HUI PERFECT SUN BLACK EX BROAD SPECTRUM SPF 50- ensulizole, octinoxate, octisalate, titanium dioxide, zinc oxide cream

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 3.5%, OCTINOXATE 7.0%, OCTISALATE 4.5%, TITANIUM DIOXIDE 4.4%, ZINC OXIDE 9.71%

PURPOSE

Sunscreen

USES

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), may decrease 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 long-sleeved shirts, pants, hats, and sunglasses.
 - Children under 6 months: Ask a doctor.

OTHER INFORMATION

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

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, DIPROPYLENE GLYCOL, GLYCERIN, DICAPRYLYL CARBONATE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, TROMETHAMINE, DIMETHICONE, PANTHENOL, CHRYSIN, GALANTHUS NIVALIS SEED EXTRACT, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DISTEARDIMONIUM HECTORITE, ALUMINUM HYDROXIDE, STEARIC ACID, ZINC STEARATE, SORBITAN SESQUIOLEATE, DIMETHICONE/PEG-10/15 CROSSPOLYMER, GLYCERYL CAPRYLATE, HYDROGEN DIMETHICONE, DISTEARYLDIMONIUM CHLORIDE, ETHYLHEXYLGLYCERIN, TRISODIUM EDTA, TRIETHOXYCAPRYLYLSILANE, DIPHENYLSILOXY PHENYL TRIMETHICONE, TRIETHOXYSILOXYETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, MICA, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499), FRAGRANCE

PRINCIPAL DISPLAY PANEL

O HUI Perfect Sun Black EX

Sunscreen Broad Spectrum SPF 50+

1.69 fl oz / 50 ml



O HUI Perfect Sun Black EX
Broad Spectrum SPF 50+

O HUI

chrysin™
extra mild
tinted sunscreen
UV protection

PERFECT SUN
BLACK EX

Broad Spectrum SPF 50+

1.69 fl oz / 50 mL

Distributed by
LG Household &
Health Care America Inc.
Santa Fe Springs, CA 90670 USA
Questions : 1-888-498-9004

MADE IN KOREA

www.ohui.co.kr

Drug Facts

Active ingredients	Purpose
Ensilazole 3.5%	Sunscreen
Octinoxate 7.0%	Sunscreen
Octisalate 4.5%	Sunscreen
Titanium Dioxide 4.4%	Sunscreen
Zinc Oxide 9.71%	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 or irritation develops and lasts.

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 long-sleeve shirts, pants, hats, and sunglasses.
 - Children under 6 months of age: Ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Water, Cyclopentasiloxane, Dipropylene Glycol, Glycerin, Dicaprylyl Carbonate, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Tromethamine, Dimethicone, Panthenol, Chrysin, Galanthus Nivalis Seed Extract, Dimethicone/Vinyl Dimethicone Crosspolymer, Distearidimonium Hectorite, Aluminum Hydroxide, Stearic Acid, Zinc Stearate, Sorbitan Sesquioleate, Dimethicone/PEG-10/15 Crosspolymer, Glyceryl Caprylate, Hydrogen Dimethicone, Distearylidimonium Chloride, Ethylhexylglycerin, Trisodium EDTA, Triethoxycaprylylsilane, Diphenylsiloxy Phenyl Trimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499), Fragrance

Questions? Call 1-888-498-9004

50707389



O HUI PERFECT SUN BLACK EX BROAD SPECTRUM SPF 50

ensulizole, octinoxate, octisalate, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53208-604
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.2 g in 50 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	1.75 g in 50 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 50 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.86 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
TROMETHAMINE (UNII: 023C2WHX2V)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
CHRYSIN (UNII: 3CN01F5ZJ5)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE (UNII: 92RU3N3Y10)	
GLYCERIN (UNII: PDC6A3C0OX)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PANTHENOL (UNII: WV9CM0O67Z)	
GALANTHUS NIVALIS SEED (UNII: SJ1FOL985M)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
DISTEARYLDIMONIUM (UNII: 251IW5I21C)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53208-604-01	1 in 1 CARTON	06/01/2017	
1		50 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	06/01/2017	

Labeler - LG Household and Health Care Inc (688276187)**Establishment**

Name	Address	ID/FEI	Business Operations
LG Household and Health Care Inc		688276187	manufacture(53208-604)

Establishment

Name	Address	ID/FEI	Business Operations
ZENISCE Co.Ltd.		690188305	manufacture(53208-604)

Revised: 6/2017

LG Household and Health Care Inc