

DOMINAS DARK SPOT TINTED SUNSCREEN- octisalate, octocrylene, titanium dioxide, zinc oxide cream
LG H&H CO., LTD.

Active Ingredients

Octisalate 2.5%

Octocrylene 4%

Titanium Dioxide 1.53%

Zinc Oxide 8.73%

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

Warning

For external use only.

Do not use

Do not use on damaged or broken skin.

When Using

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

Keep out of reach of children.

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure

- children under 6 months of age: ask a doctor
- 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 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.-2p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Other Information

- protect the product in this container from excessive heat and direct sun
- the product may stain certain types of fabrics

Questions?

1-866-993-4709

Inactive Ingredients

WATER, DICAPRYLYL CARBONATE, HEXYL LAURATE, DIPROPYLENE GLYCOL, SORBITAN OLIVATE, GLYCERIN, CYCLOPENTASILOXANE, ISOHEXADECANE, DISTEARDIMONIUM HECTORITE, PANTHENOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, GLYCERYL CAPRYLATE, MAGNESIUM SULFATE, PEG-30 DIPOLYHYDROXYSTEARATE, FRAGRANCE, TRIETHOXYCAPRYLYLSILANE, ALUMINUM STEARATE, ALUMINA, MICA, ETHYLHEXYLGLYCERIN, STEARYL GLYCIRRHETINATE, IRON OXIDES(CI 77492), MYRISTICA FRAGRANS (NUTMEG) EXTRACT, IRON OXIDES(CI 77491), IRON OXIDES(CI 77499), MORINGA OLEIFERA SEED OIL, DIPHENYLSILOXY PHENYL TRIMETHICONE, TOCOPHEROL, TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, CHRYSIN, 1,2-HEXANEDIOL, CAMELLIA SINENSIS LEAF EXTRACT, HYDROXYCITRONELLAL, LIMONENE, LINALOOL





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octisalate, octocrylene, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53208-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.53 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.73 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
NUTMEG (UNII: AEE24M3MQ9)	
ORANGE TERPENES (UNII: 9J3RG7FX7S)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
CI 77491 (UNII: 1K09F3G675)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
ALUMINUM MONOSTEARATE (UNII: P9BC99461E)	

ALUMINA (UNII: LMI26O6933)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MICA (UNII: V8A1AW0880)	
CI 77492 (UNII: EX438O2MRT)	
TOCOPHEROL (UNII: R0ZB2556P8)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
CI 77499 (UNII: XM0M87F357)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
WATER (UNII: 059QF0KO0R)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
CHRYSLIN (UNII: 3CN01F5ZJ5)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
PANTHENOL (UNII: WW9CM0O67Z)	
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)	
LINALOOL (UNII: D81QY6I88E)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53208-302-02	1 in 1 CARTON	03/25/2025	
1	NDC:53208-302-01	50 g 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 Drug	M020	03/25/2025	

Labeler - LG H&H CO., LTD. (688276187)

Establishment

Name	Address	ID/FEI	Business Operations
fmg Co.Ltd		690188305	manufacture(53208-302)

