



ULTRA UV PROTECTIVE MINERAL DEFENCE- zinc oxide lotion
Ultraceuticals Pty Ltd

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.

ULTRACEUTICALS Ultra UV Protective Mineral Defence SPF 50+

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<p>DRUG FACTS</p> <p>Active Ingredients Purpose Zinc Oxide 12% w/w.....Sunscreen</p> <hr/> <p>Uses Helps prevent sunburn if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun.</p> <hr/> <p>Warnings</p> <hr/> <p>Do not use:</p> <ul style="list-style-type: none"> on damaged or broken skin. <hr/> <p>When using this product</p> <ul style="list-style-type: none"> keep out of eyes. Rinse with water to remove. <hr/> <p>Stop use and ask a doctor:</p> <ul style="list-style-type: none"> if skin rash occurs. <hr/> <p>For external use only.</p> <hr/> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <hr/> <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure and at least every 2 hours. children under 6 months of age: ask a doctor. 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: <ul style="list-style-type: none"> limit your time in the sun, especially from 10 a.m. – 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses reapply: <ul style="list-style-type: none"> after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours. <p>Continued on side panel ▶</p>	<p>DRUG FACTS (continued)</p> <p>Other information Protect the product in this container from excessive heat and direct sun.</p> <hr/> <p>Inactive ingredients Allantoin, Bisabolol Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caffeine, Caprylyl Glycol, Caprylyl Methicone, Carmoisine, Dimethicone, Isododecane, Lauryl PEG-10 Tri(trimethylsiloxy) silyethyl Dimethicone, Lauryl PEG-8 Dimethicone, Methylpropanediol, Niacinamide, Octyldodecyl Neopentanoate, PEG-10, Phenylpropanol, Polymethylsiloxesquioxane, Propanediol, Silica, Sodium Chloride, Sodium Hydroxide, Tetrasodium Glutamate Diacetate, Triceteareth-4 Phosphate, Tridecyl Salicylate, Water</p> <hr/> <p>Questions or comments? Toll free US: 833 703 9067 Email: advice@ultraceuticals.com.au</p> <hr/> <p>How to use: Shake well before use. Apply liberally and evenly 15 minutes before sun exposure and at least every 2 hours.</p> <p>This product does not contain nanoparticles.</p> <hr/> <p>Made in USA</p> <hr/> <p>Distributed by: Ultraceuticals Pty Ltd Suite 2, Level 4, 436-484 Victoria Rd Gladesville NSW 2111 AUSTRALIA</p> <hr/> <p>© Ultraceuticals Pty Ltd 2019</p> <p>Ultraceuticals is a trademark and brand of Ultraceuticals Pty Ltd.</p> 	<p style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: 48px; font-weight: bold; letter-spacing: 0.5em;">ULTRACEUTICALS</p> <p>Ultra UV Protective Mineral Defence SPF 50+</p> <hr/> <p>High Protection Sunscreen</p> <p>Broad Spectrum SPF 50+</p> <p>Water Resistant (40 minutes)</p> <p>For Normal, Dry, or Oily Skin</p> <p>Sunscreen Cream</p> <p>100 mL / 3.38 fl. OZ.</p>	<p>Ultraceuticals products are developed to provide optimal results when professionally recommended.</p> <hr/> <p>I have spent over twenty years as a cosmetic physician working with clients exposed to one of the harshest conditions in the world - the Australian sun. I established Ultraceuticals in 1998 as a concise science based skincare range to address the major skin concerns and to deliver real and visible results. Ultraceuticals products are developed using high concentrations of proven and potent ingredients in cutting edge consumer trialled formulations. Ultraceuticals is available solely where trained skincare advisors can provide professional recommendation.</p>  <p>Dr. Geoffrey Heber Founder and Director Fondateur et Directeur</p>
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ULTRA UV PROTECTIVE MINERAL DEFENCE			
zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10028-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	127 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISODODECANE (UNII: A8289P68Y2)	
CAFFEINE (UNII: 3G6A5W338E)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X5118RD4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
CARNOSINE (UNII: 8HO6PVN24W)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10028-060-02	1 in 1 CARTON	01/10/2020	

1	NDC:10028-060-01	100 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10028-060-04	1 in 1 CARTON	01/10/2020	
2	NDC:10028-060-03	5 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 not final	part352	01/10/2020	

Labeler - Ultraceuticals Pty Ltd (744068995)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(10028-060)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(10028-060) , manufacture(10028-060)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(10028-060) , pack(10028-060)

Revised: 3/2023

Ultraceuticals Pty Ltd