

DAILY DEFENSE TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
LEDUC, XUANTO MD

DRUG FACTS (cont)

• **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 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS: Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics

MANUFACTURED FOR:
 Leduc Medical Group
 Fountain Valley, CA 92708



DAILY DEFENSE TINTED MINERAL SUNSCREEN

SPF 50 Broad Spectrum
 Water Resistant (40 Minutes)

DRUG FACTS

ACTIVE INGREDIENTS: Titanium Dioxide 10%
 Zinc Oxide 3%

PURPOSE: Sunscreen
 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. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: Ask a doctor

Net Wt 1.8 oz/ 53 g

DAILY DEFENSE TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85691-258(NDC:58892-258)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0K00R)	
CETEARETH-20 (UNII: YRC528SWJY)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
CI 77491 (UNII: 1K09F3G675)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
GLYCERIN (UNII: PDC6A3C00X)	
CI 77492 (UNII: EX438O2MRT)	
CI 77499 (UNII: XM0M87F357)	
ISODODECANE (UNII: A8289P68Y2)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85691-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/13/2024	

Labeler - LEDUC, XUANTO MD (181170408)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85691-258)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85691-258)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85691-258)

Revised: 12/2025

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