

CLINIQUE FOR MEN UV DEFENSE BROAD SPECTRUM SPF50- titanium dioxide and zinc oxide lotion

CLINIQUE LABORATORIES LLC

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.

CLINIQUE FOR MEN UV DEFENSE BROAD SPECTRUM SPF50

Drug Facts

Active Ingredients

Titanium dioxide 6.2%

Zinc oxide 4.0%

Purpose

Sunscreen

Use

helps prevent sunburn

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 occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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.–2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses.
- children under 6 months of age: ask a doctor

Inactive ingredients

water/aqua/eau•dimethicone•butyloctyl salicylate•polydiethyl siloxane•c12-15 alkyl benzoate•isononyl isononanoate•diethylhexyl succinate•neopentyl glycol diheptanoate•methyl trimethicone•butylene

glycol•ethylhexyl methoxycrylene•lauryl peg-9 polydimethylsiloxylethyl dimethicone•silica•laureth-4•cetyl peg/ppg-10/1 dimethicone•dipentaerythryl tri-polyhydroxystearate•dimethicone silylate•hydrolyzed wheat protein/pvp crosspolymer•isostearic acid•caprylyl glycol•dimethicone crosspolymer-3•polyhydroxystearic acid•triethoxycaprylylsilane•dimethicone/peg-10/15 crosspolymer•dipropylene glycol•phenoxyethanol•iron oxides (ci 77491)•iron oxides (ci 77492) [iln41056]

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

**CLINIQUE
FOR MEN**

**UV defense
broad spectrum
SPF 50**

1 FL.OZ.LIQ./30 ml e



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TP 203

2025 5039

Allergy Tested.
100% Fragrance Free.
Ophthalmologist Tested.
Patent-pending technology.
 Ultra-lightweight, high-level UVA/UVB protection that can be worn comfortably every day to help prevent the signs of aging. Patent-pending Invisible Screen™ technology forms a protective shield that's virtually invisible on all skin tones. Oil-free. Shake well.

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Drug Facts (cont'd)

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Inactive ingredients
 water/aqua/eau • butyloctyl dimethicone • butyl salicylate • polydimethylsiloxane • c12-15 alkyl benzoate • isononyl isononanoate • diethylhexyl succinate • neopentyl glycol diheptanoate • methyl ▶

CLINIQUE FOR MEN

UV defense broad spectrum SPF 50

1 FL.OZ.LIQ./30 ml e

Drug Facts (cont'd)
 trimethicone • butylene glycol • ethylhexyl methoxycrylate • lauryl peg-9 polydimethylsiloxyethyl dimethicone • silica • laureth-4 • cetyl peg/ppg-10/1 dimethicone • dipentaerythrityl tri-polyhydroxystearate • dimethicone silylate • hydrolyzed wheat protein/ppv crosspolymer • isostearic acid • caprylyl glycol • dimethicone crosspolymer-3 • polyhydroxystearic acid • triethoxycaprylylsilane • dimethicone/peg-10/15 crosspolymer • dipropylene glycol • phenoxyethanol • iron oxides (ci 77491) • iron oxides (ci 77492) [In41056]

Other information
 Protect the product in this container from excessive heat and direct sun

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Z5WW-01-1111

CLINIQUE FOR MEN UV DEFENSE BROAD SPECTRUM SPF50
 titanium dioxide and zinc oxide lotion
Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-046	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	titanium dioxide (UNII: 15FIX9V2JP) (titanium dioxide - UNII:15FIX9V2JP)	titanium dioxide	0.06696 g in 100 mL	
	zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	0.0432 g in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	water (UNII: 059QF0KO0R)			
	dimethicone (UNII: 92RU3N3Y1O)			
	butyloctyl salicylate (UNII: 2EH13UN8D3)			
	alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)			
	isononyl isononanoate (UNII: S4V5BS6GCX)			
	diethylhexyl succinate (UNII: 69W9UMG3P8)			
	neopentyl glycol diheptanoate (UNII: 5LKW3C543X)			
	methyl trimethicone (UNII: S73ZQI0GXM)			
	butylene glycol (UNII: 3XUS85K0RA)			
	ethylhexyl methoxycrylene (UNII: S3KFG6Q5X8)			
	lauryl peg-9 polydimethylsiloxyethyl dimethicone (UNII: 25G622K2RA)			
	silicon dioxide (UNII: ETJ7Z6XBU4)			
	laureth-4 (UNII: 6HQ855798J)			
	isostearic acid (UNII: X33R8U0062)			
	caprylyl glycol (UNII: 00YIU5438U)			
	triethoxycaprylylsilane (UNII: LDC331P08E)			
	dipropylene glycol (UNII: E107L85C40)			
	phenoxyethanol (UNII: HIE492ZZ3T)			
	ferric oxide red (UNII: 1K09F3G675)			
	ferric oxide yellow (UNII: EX438O2MRT)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-046-01	1 in 1 CARTON	04/01/2015	
1		30 mL in 1 BOTTLE; 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	04/01/2015	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-046) , REPACK(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-046) , REPACK(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-046) , REPACK(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-046)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-046)