

**EVEN BETTER COMPACT MAKEUP BROAD SPECTRUM SPF15- titanium dioxide cream
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.

**EVEN BETTER COMPACT MAKEUP
BROAD SPECTRUM SPF15**

Drug Facts

Active ingredient

Titanium Dioxide 3.80%

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 doctor

Inactive ingredients

ethylhexyl palmitate • silica • phenyl trimethicone • cetyl dimethicone • tribehenin • squalane • glycereth-8 hydroxystearate • trimethylsiloxysilicate • arachidyl propionate • ozokerite • lauryl methacrylate/glycol dimethacrylate crosspolymer • tetrahexyldecyl ascorbate • ascorbyl palmitate •

trihydroxystearin • tocopheryl acetate • caprylyl glycol • sorbitan sesquioleate • triethoxycaprylylsilane
• simethicone • disteardimonium hectorite • [+/- iron oxides (ci 77491, ci 77492, ci 77499) • titanium
dioxide (ci 77891) • zinc oxide (ci 77947) • mica] [iln39622]

Other information

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

DIST. NEW YORK, N.Y. 10022

PRINCIPAL DISPLAY PANEL - 10 g Tube Carton

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CLINIQUE

even better

compact makeup

broad spectrum

SPF 15

evens and corrects

POIDS NET WT. .35 OZ./ 10 g e



EVEN BETTER COMPACT MAKEUP BROAD SPECTRUM SPF15

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	3.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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ethylhexyl palmitate (UNII: 2865993309)
silicon dioxide (UNII: ETJ7Z6XBU4)
phenyl trimethicone (UNII: DR0K5NOJ4R)
tribehenin (UNII: 8OC9U7TQZ0)
squalane (UNII: GW89575KF9)
arachidyl propionate (UNII: QV5DAH3MSB)
lauryl methacrylate/glycol dimethacrylate crosspolymer (UNII: EX0F4CZ66H)
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)
ascorbyl palmitate (UNII: QN83US2B0N)
trihydroxystearin (UNII: 06YD7896S3)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
caprylyl glycol (UNII: 00YIU5438U)
sorbitan sesquioleate (UNII: 0W8RRI5W5A)
triethoxycaprylylsilane (UNII: LDC331P08E)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
zinc oxide (UNII: SOI2LOH54Z)
mica (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-018-01	1 in 1 CARTON	10/01/2012	
1		10 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 NOT FINAL	part352	10/01/2012	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-018) , REPACK(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-018) , REPACK(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-018) , REPACK(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-018)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-018)

Revised: 11/2019

CLINIQUE LABORATORIES LLC