

**ACNE BB BROAD SPECTRUM SPF 40- octinoxate, octisalate, and 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.*

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**ACNE SOLUTIONS BB CREAM BROAD SPECTRUM SPF 40**

***Drug Facts***

**Active ingredients**

Octinoxate 7.5%

Octisalate 2%

Titanium Dioxide 1.6%

**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 • 'methyl trimethicone • 'alcohol' • ethylhexyl palmitate • 'peg-9

polydimethylsiloxylethyl dimethicone • propanediol • glycerin • glyceryl caprylate • peg-3 dimethicone • dimethicone • tocopheryl acetate • lecithin • triethoxycaprylylsilane • stearyl glycyrrhettinate • sorbitan sesquiosostearate • sodium hyaluronate • pyridoxine hcl • stearic acid • hesperidin methyl chalcone • palmitoyl tetrapeptide-7 • sodium chloride • aluminum hydroxide • steareth-20 • dipeptide-2 • silica • sodium citrate • phenoxyethanol • [+/- mica • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499) • titanium dioxide (ci 77891)] [iln41343]

### **Other information**

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

### **PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton**

**acne**

**C**

**CLINIQUE**

**acne solutions**

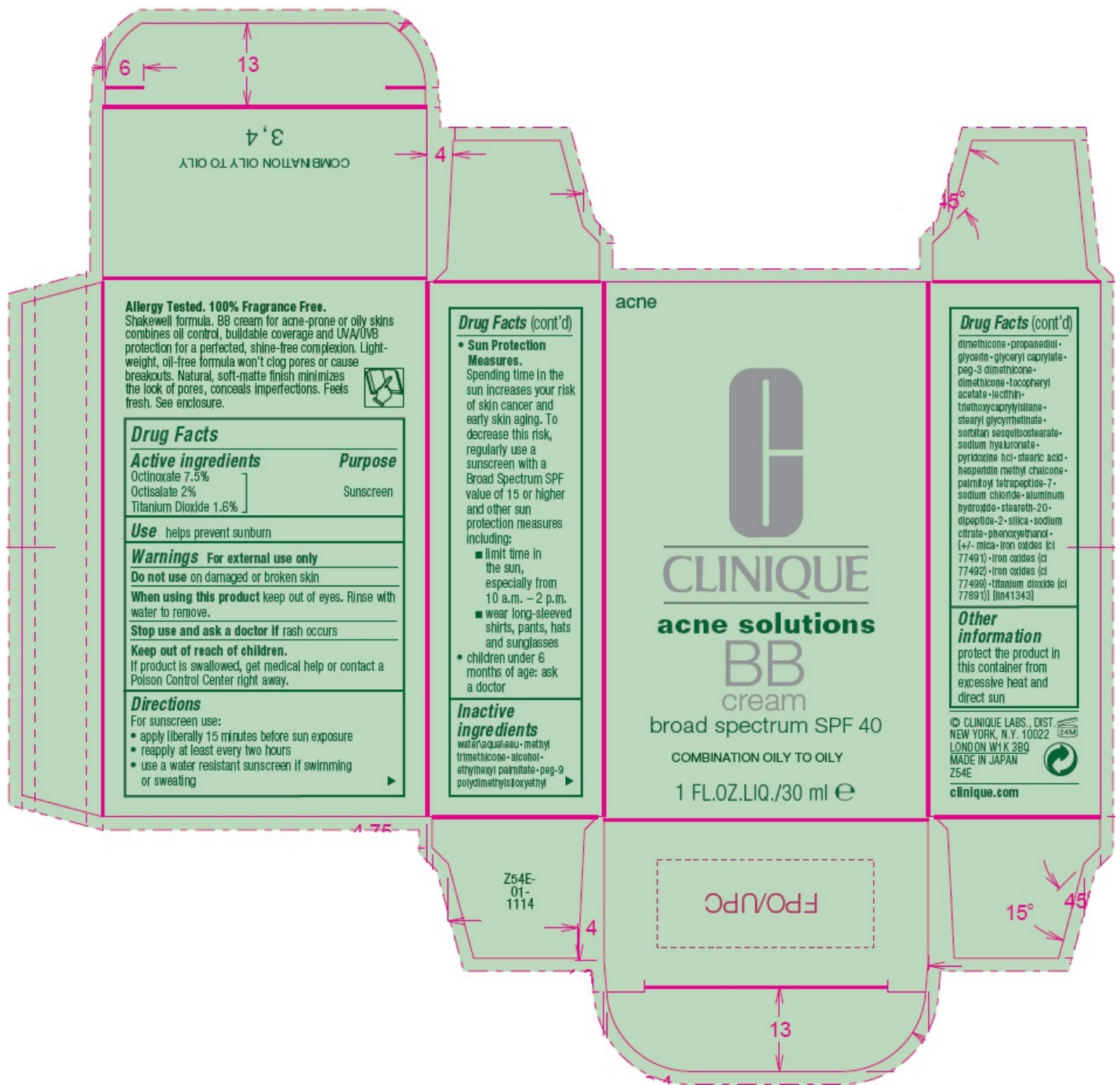
**BB**

cream

broad spectrum SPF 40

COMBINATION OILY TO OILY

1 FL.OZ.LIQ./30 ml e



## ACNE BB BROAD SPECTRUM SPF 40

octinoxate, octisalate, and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-044
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.08175 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.0218 g in 100 mL

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.01744 g in 100 mL
<b>Inactive Ingredients</b>		
Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)		
ALCOHOL (UNII: 3K9958V90M)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)		
PROPANEDIOL (UNII: 5965N8W85T)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)		
HYALURONATE SODIUM (UNII: YSE9PPT4TH)		
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
HESPERIDIN METHYLCHALCONE (UNII: 4T2GVA922X)		
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
STEARETH-20 (UNII: L0Q8IK9E08)		
VALYLTRYPTOPHAN (UNII: 3G64B4AFQN)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
MICA (UNII: V8A1AW0880)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSO FERRIC OXIDE (UNII: XM0M87F357)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-044-01	1 in 1 CARTON	11/01/2014	
1		30 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	11/01/2014	

**Labeler** - CLINIQUE LABORATORIES LLC (044475127)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-044) , REPACK(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-044) , REPACK(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-044) , REPACK(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-044)

## Establishment

Name	Address	ID/FEI	Business Operations
JO COSMETICS		691485222	MANUFACTURE(49527-044)