

**CLARINS EVERLASTING CUSHION LONG WEARING AND HYDRATING FOUNDATION
BROAD SPECTRUM SPF 50 108 RETAIL- ensulizole, titanium dioxide emulsion
LABORATOIRES CLARINS**

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.

**CLARINS - EVERLASTING CUSHION LONG-WEARING & HYDRATING FOUNDATION -
BROAD SPECTRUM SPF 50 - 108 Retail**

Drug Facts

Active Ingredients:

ENSULIZOLE: 2.7 %

TITANIUM DIOXIDE: 6.2 %

Purpose:

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.

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:

- apply liberally 15 minutes before sun exposure.
- apply to all skin exposed to the sun.
- children under 6 months: 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 broad spectrum SPF 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.
- reapply at least every 2 hours.
- use a water resistant sunscreen if swimming or sweating.

Inactive Ingredients:

AQUA/WATER/EAU . CYCLOPENTASILOXANE . PHENYL TRIMETHICONE .
CYCLOHEXASILOXANE . BUTYLENE GLYCOL . DIPENTAERYTHRITYL HEXA C5-9 ACID
ESTERS . TRIETHYLHEXANOIN . CETYL PEG/PPG-10/1 DIMETHICONE . GLICERIN .
DIMETHICONE . NIACINAMIDE . TROMETHAMINE . 1,2-HEXANEDIOL . SORBITAN
SESQUIOLEATE . STEARIC ACID . DIMETHICONE/PEG-10/15 CROSSPOLYMER . NYLON-12 .
PEG-30 DIPOLYHYDROXYSTEARATE . SODIUM CHLORIDE . ZINC STEARATE . ALUMINUM
HYDROXIDE . DISTEARYLDIMONIUM CHLORIDE . PARFUM/FRAGRANCE . TOCOPHERYL
ACETATE . BIS-VINYL DIMETHICONE/DIMETHICONE COPOLYMER . DISTEARDIMONIUM
HECTORITE . TRIETHOXYCAPRYLYLSILANE . ADENOSINE . PALMITOYL PROLINE .
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE .
CHENOPODIUM QUINOA SEED EXTRACT . MAGNESIUM PALMITOYL GLUTAMATE .
SODIUM PALMITOYL SARCOSINATE . CERAMIDE 3 . PALMITIC ACID . HYDROGENATED
LECITHIN . LAPSANA COMMUNIS FLOWER/ LEAF/STEM EXTRACT . DIPROPYLENE
GLYCOL . GLYCERETH-20 . CAMELLIA SINENSIS LEAF EXTRACT . PEG-10
RAPESEED STEROL . GLYCERYL STEARATE . SODIUM BENZOATE . PHENOXYETHANOL.
+/-MAY CONTAIN/PEUT CONTENIR : MICA . SILICA . CI 77891/TITANIUM DIOXIDE . CI
77491/CI 77492/CI 77499/IRON OXIDES. [MS3256A2]

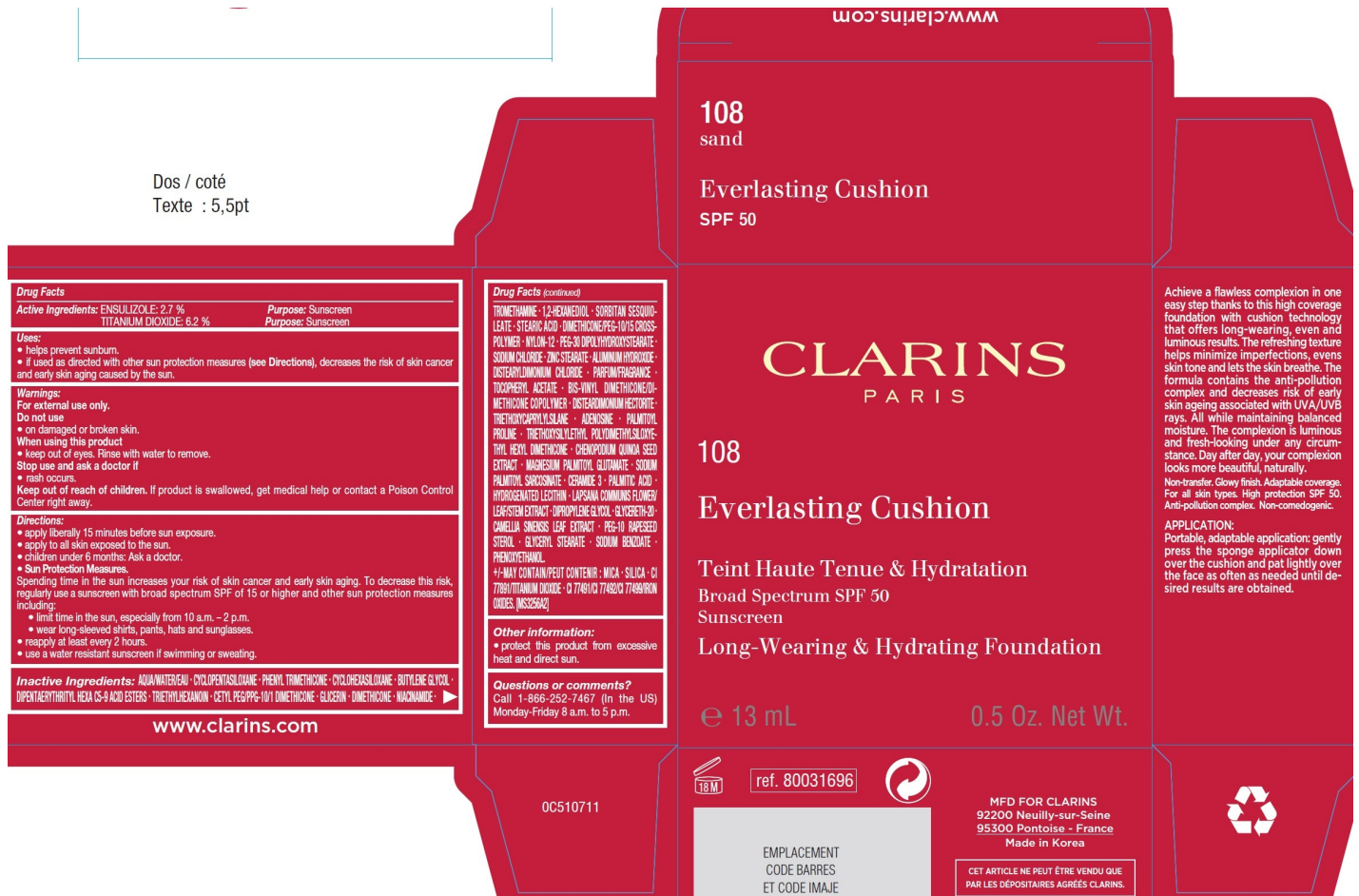
Other information:

- protect this product from excessive heat and direct sun.

Questions or comments?

Call 1-866-252-7467 (In the US) Monday-Friday 8 a.m. to 5 p.m.

Package Labeling: (58668-1726-0)



CLARINS EVERLASTING CUSHION LONG WEARING AND HYDRATING FOUNDATION BROAD SPECTRUM SPF 50 108 RETAIL

ensulizole, titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58668-1726
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9D1I1W42) (ENSULIZOLE - UNII:9YQ9D1I1W42)	ENSULIZOLE	27 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	62 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPENTAERYTHRITYL HEXA C5-9 ACID ESTERS (UNII: D818OLQ51Z)	

TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)
GLYCERIN (UNII: PDC6A3C0OX)
DIMETHICONE (UNII: 92RU3N3Y1O)
NIACINAMIDE (UNII: 25X51I8RD4)
TROMETHAMINE (UNII: 023C2WHX2V)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)
STEARIC ACID (UNII: 4ELV7Z65AP)
NYLON-12 (UNII: 446U8J075B)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ZINC STEARATE (UNII: H92E6QA4FV)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
ADENOSINE (UNII: K72T3FS567)
PALMITOYL PROLINE (UNII: I49727TDYF)
MAGNESIUM PALMITOYL GLUTAMATE (UNII: DH37YM1F48)
SODIUM PALMITOYL SARCO SINATE (UNII: 7297LY09YF)
CERAMIDE 3 (UNII: 4370DF050B)
PALMITIC ACID (UNII: 2V16EO95H1)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
GLYCERETH-20 (UNII: GJ57297I4F)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58668-1726-0	1 in 1 BOX	08/01/2018	
1		13 mL in 1 JAR; 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	08/01/2018	

Labeler - LABORATOIRES CLARINS (266317555)