

**CLE DE PEAU BEAUTE SYNACTIF DAYTIME MOISTURIZER- ensulizole and octinoxate cream**  
**SHISEIDO CO., LTD.**

*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.*

-----

**cle de peau BEAUTE SYNACTIF DAYTIME MOISTURIZER**

**Drug Facts**

| <b>Active ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
| ENSULIZOLE 2.0%           | Sunscreen      |
| OCTINOXATE 4.9%           | Sunscreen      |

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection

**Warnings**

**For external use only**

**When using this product**

- keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

- rash or irritation develops and lasts.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply generously before sun exposure and as needed.
- apply and reapply as directed to avoid lowering protection.
- apply to all skin exposed to the sun.
- children under 6 months of age: ask a doctor

**Inactive ingredients**

WATER, GLYCERIN, BUTYLENE GLYCOL, CYCLOMETHICONE, DIPROPYLENE GLYCOL, SILICA, DIMETHICONE, TRIETHYLHEXANOIN, DIPHENYLSILOXY PHENYL TRIMETHICONE, BEHENYL ALCOHOL, BEHENETH-20, TRIETHANOLAMINE, METHYL AMINOMETHYLCYCLOHEXANE CARBOXAMIDE HCl, XANTHAN GUM, TOCOPHERYL ACETATE, SODIUM HYALURONATE, SODIUM ACETYLATED HYALURONATE, LAURYL BETAINE, BUPLEURUM FALCATUM ROOT EXTRACT, UNCARIA GAMBIR EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, STEARYL ALCOHOL, SODIUM METAPHOSPHATE, CELLULOSE GUM, TRISODIUM EDTA, ALUMINUM HYDROXIDE, ISOSTEARIC ACID, BHT, ALCOHOL, TOCOPHEROL, PHENOXYETHANOL, SODIUM BENZOATE, FRAGRANCE, TITANIUM DIOXIDE, IRON OXIDES

**Questions?**

**1-800-906-7503**

Distributed by  
SHISEIDO COSMETICS (AMERICA) LTD.  
NEW YORK, NY 10022

**PRINCIPAL DISPLAY PANEL - 20mL Bottle Carton**

**SYNACTIF**

*Daytime moisturizer*

*SPF 17 sunscreen*

20mL NET WT. .75 OZ.

Daytime moisturizer



**P**

**SYNACTIF**

*Daytime moisturizer*  
*SPF 17 sunscreen*

20mL NET WT. .75 OZ.

**Drug Facts (continued)**

**Directions**

- apply generously before sun exposure.
- apply and reapply as directed to avoid lowering protection.
- apply to all skin exposed to the sun.
- children under 6 months of age: ask a doctor

**Inactive ingredients**

WATER • GLYCERIN • BUTYLENE GLYCOL • CYCLOMETHICONE •  
DIPROPYLENE GLYCOL • SILICA • DIMETHOONE • TRIETHYLHEXANON •  
DIPHENYLSILOXY PHENYL TRIMETHICONE • BEHENYL ALCOHOL •  
BENZETH-20 • TRIETHANOLAMINE •  
METHYL AMINOMETHYL CYCLOHEPANE CARBOXYMIDE HCl •  
XANTHAN GUM • TOCOPHERYL ACETATE • SODIUM HYALURONATE •  
SODIUM ACETYLATED HYALURONATE • LAURYL BETAINE •  
BUPLEURUM FALCATUM ROOT EXTRACT • UNCARIA GAMBIR EXTRACT •  
CAMELLIA SINENSIS LEAF EXTRACT • STEARYL ALCOHOL •  
SODIUM METAPHOSPHATE • CELLULOSE GUM • TRISODIUM EDTA •  
ALUMINUM HYDROXIDE • ISOSTEARIC ACID • BHT • ALCOHOL •  
TOCOPHEROL • PHENOXYETHANOL • SODIUM BENZOATE • FRAGRANCE •  
TITANIUM DIOXIDE • OR G006S •

**Questions?**

1-800-906-7503

47.5X47.5X71  
1234567890

clé de peau  
BEAUTÉ  
SYNACTIF  
DAYTIME MOISTURIZER  
READ INSERTION.

Distributed by  
SHISEIDO COSMETICS (AMERICA) LTD.  
NEW YORK, NY 10022  
MADE IN JAPAN  
NEW YORK · PARIS · MILANO  
G.L.O. 32762  
www.cledepeau-beaute.com

### Drug Facts

| Active ingredients   | Purpose   |
|----------------------|-----------|
| ENSULIZOLE 2.0%..... | Sunscreen |
| OCTINOXATE 4.9%..... | Sunscreen |

### Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection ▶



### Drug Facts (continued)

#### Warnings

For external use only

#### When using this product

- keep out of eyes.  
Rinse with water to remove.

#### Stop use and ask a doctor if

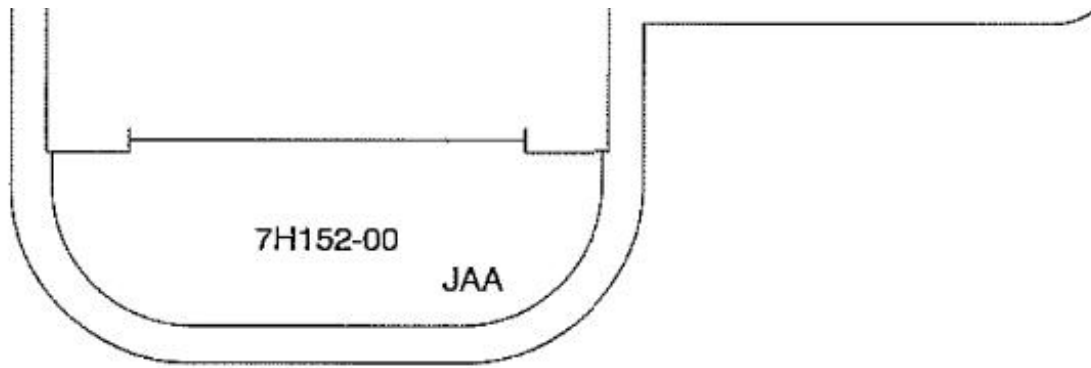
- rash or irritation develops and lasts.

#### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. ▶

縮小サイズ0.85倍 8mm×5-  
14mm×33mm

7 29238 32762 \*



## CLE DE PEAU BEAUTE SYNACTIF DAYTIME MOISTURIZER

ensulizole and octinoxate cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:52685-380 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                         | Basis of Strength | Strength           |
|-------------------------------------------------------------------------|-------------------|--------------------|
| <b>Ensulizole</b> (UNII: 9 YQ9 D11W42) (Ensulizole - UNII:9 YQ9 D11W42) | Ensulizole        | 430 mg in 21.52 g  |
| <b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)     | Octinoxate        | 1054 mg in 21.52 g |

### Inactive Ingredients

| Ingredient Name                                           | Strength |
|-----------------------------------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0K00R)                           |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C00X)                        |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)                 |          |
| <b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)                  |          |
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)              |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                 |          |
| <b>TRIETHYLHEXANO IN</b> (UNII: 7K3W1BIU6K)               |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                     |          |
| <b>DOCOSANOL</b> (UNII: 9G1OE216XY)                       |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                |          |
| <b>TROLAMINE</b> (UNII: 9O3K93S3TK)                       |          |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)                 |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                  |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                     |          |
| <b>SODIUM POLYMETAPHOSPHATE</b> (UNII: P1BM4ZH95L)        |          |
| <b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)   |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) |          |
| <b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)               |          |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)              |          |
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)              |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                |          |

|                                             |  |
|---------------------------------------------|--|
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT)      |  |
| ISO STEARIC ACID (UNII: X33R8U0062)         |  |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) |  |
| LAURYL BETAINE (UNII: Y4P927Q133)           |  |
| ALCOHOL (UNII: 3K9958V90M)                  |  |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)       |  |
| BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)  |  |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)           |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)          |  |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:52685-380-10 | 1 in 1 CARTON       |                      |                    |
| 1         |                  | 21.52 g in 1 BOTTLE |                      |                    |

| Marketing Information   |                                          |                      |                    |
|-------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part352                                  | 11/01/2009           |                    |

**Labeler** - SHISEIDO CO., LTD. (690536453)

| Establishment      |         |           |                                              |
|--------------------|---------|-----------|----------------------------------------------|
| Name               | Address | ID/FEI    | Business Operations                          |
| SHISEIDO CO., LTD. |         | 695087684 | MANUFACTURE(52685-380) , ANALYSIS(52685-380) |

Revised: 4/2012

SHISEIDO CO., LTD.