

**OBAGI-C FX SYSTEM NORMAL-OILY SKIN BRIGHTENING SYSTEM WITH ARBUTIN-homosalate, octisalate, and zinc oxide**

**Obagi Cosmeceuticals LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).*

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**OBAGI-C<sup>®</sup> FX SYSTEM NORMAL-OILY SKIN BRIGHTENING SYSTEM WITH ARBUTIN**

***Drug Facts***

| <b><i>Active ingredients</i></b> | <b><i>Purpose</i></b> |
|----------------------------------|-----------------------|
| Homosalate 10%                   | Sunscreen             |
| Octisalate 5%                    | Sunscreen             |
| Zinc Oxide 16.5%                 | 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

**Stop use and ask a doctor** if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

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

**Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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: Ask a doctor

**Other information**

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

**Inactive ingredients**

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Oliviate, Silica, Polyglyceryl-6 Polyrininoate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

**Questions or comments?**

**1.800.636.7546**

Monday–Friday 9 a.m.–4 p.m. Pacific Time

Distributed by Obagi Cosmeceuticals LLC,  
Long Beach, CA 90806

**PRINCIPAL DISPLAY PANEL - Kit Carton**

OBAGI®  
MEDICAL

OBAGI-C® FX SYSTEM

NORMAL OILY

Skin Brightening System  
with Arbutin



Complete skin care system specifically formulated for normal to oily skin that includes products containing skin-hydrating actives.

## OBAGI-C® FX SYSTEM



C-Clearing Gel 6 fl. oz. (177 mL) **AM+PM**  
 Hydrating and purifying for the skin's product ingredients, while also promoting and supporting daily morning and evening skin care with moisture locking, radiance and clarity. Use twice daily, morning and evening. Apply to damp, clean skin and pat dry. Avoid use on sunburned or irritated skin. For external use only. **Warnings:** Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use with retinoids or other topical acne treatments. Use as directed. Do not use on sunburned or irritated skin. For external use only.

1 fl. oz. (30 mL) **AM**  
 Skin brightening serum formulated with 4% vitamin and 10% L-ascorbic acid to help minimize the appearance of skin aging or other skin conditions. **Directions:** Use once daily in the morning. Apply to dry skin. **Warnings:** Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use on sunburned or irritated skin. For external use only.

1 fl. oz. (30 mL) **AM**  
 Skin brightening serum formulated with 4% vitamin and 10% L-ascorbic acid to help minimize the appearance of skin aging or other skin conditions. **Directions:** Use once daily in the morning. Apply to dry skin. **Warnings:** Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use on sunburned or irritated skin. For external use only.

| Drug Facts  |   |
|---|---|
| <p>5.1 oz. (143 mL) <b>AM</b><br/>           Skin Shield Moisturizer Broad Spectrum SPF 50<br/>           Moisturizer with SPF 50. Broad spectrum UVA and UVB protection. Helps reduce the appearance of skin aging and other skin conditions. <b>Directions:</b> Apply to clean, dry skin. Reapply every 2 hours. For external use only.</p>   | <p>1 fl. oz. (30 mL) <b>AM</b><br/>           Skin Brightening Serum<br/>           Skin brightening serum formulated with 4% vitamin and 10% L-ascorbic acid to help minimize the appearance of skin aging or other skin conditions. <b>Directions:</b> Use once daily in the morning. Apply to dry skin. <b>Warnings:</b> Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use on sunburned or irritated skin. For external use only.</p> |
| <p>1 fl. oz. (30 mL) <b>AM</b><br/>           Skin Brightening Serum<br/>           Skin brightening serum formulated with 4% vitamin and 10% L-ascorbic acid to help minimize the appearance of skin aging or other skin conditions. <b>Directions:</b> Use once daily in the morning. Apply to dry skin. <b>Warnings:</b> Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use on sunburned or irritated skin. For external use only.</p> | <p>1 fl. oz. (30 mL) <b>AM</b><br/>           Skin Brightening Serum<br/>           Skin brightening serum formulated with 4% vitamin and 10% L-ascorbic acid to help minimize the appearance of skin aging or other skin conditions. <b>Directions:</b> Use once daily in the morning. Apply to dry skin. <b>Warnings:</b> Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with lukewarm water. Cautions: Do not use on sunburned or irritated skin. For external use only.</p> |
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NO COATING

NORMAL OILY

NO COATING

NO  
COATING

## OBAGI-C FX SYSTEM NORMAL-OILY SKIN BRIGHTENING SYSTEM WITH ARBUTIN

homosalate, octisalate, and zinc oxide kit

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62032-536 |
|--------------|----------------|--------------------|---------------|

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:62032-536-57 | 1 in 1 CARTON       | 12/02/2019           |                    |

### Quantity of Parts

| Part # | Package Quantity  | Total Product Quantity |
|--------|-------------------|------------------------|
| Part 1 | 1 BOTTLE, GLASS   | 30 mL                  |
| Part 2 | 1 BOTTLE, PLASTIC | 57 g                   |
| Part 3 | 1 TUBE            | 85 g                   |
| Part 4 | 1 BOTTLE, PLASTIC | 177 mL                 |
| Part 5 | 1 BOTTLE, PLASTIC | 198 mL                 |

### Part 1 of 5

## OBAGI -C FX SYSTEM C-CLARIFYING SERUM SKIN BRIGHTENING SERUM

lotions, oils, powders, and creams liquid

## Product Information

Route of Administration TOPICAL

## Other Ingredients

| Ingredient Kind | Ingredient Name                          | Quantity |
|-----------------|--|----------|
| INGR            | PROPYLENE GLYCOL (UNII: 6DC9Q167V3)      |          |
| INGR            | WATER (UNII: 059QF0K00R)                 |          |
| INGR            | ASCORBIC ACID (UNII: PQ6CK8PD0R)         |          |
| INGR            | SODIUM LAURYL SULFATE (UNII: 368GB5141J) |          |
| INGR            | PROPYLENE CARBONATE (UNII: 8D08K3S51E)   |          |
| INGR            | ALCOHOL (UNII: 3K9958V90M)               |          |
| INGR            | DIPROPYLENE GLYCOL (UNII: E107L85C40)    |          |
| INGR            | ARBUTIN (UNII: C5INA23HXF)               |          |

## Packaging

| # | Item Code | Package Description   | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 |           | 1 in 1 CARTON   |                      |                    |
| 1 |           | 30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| COSMETIC           |  | 01/01/2010           |                    |

## Part 2 of 5

### OBAGI -C FX SYSTEM C-THERAPY NIGHT SKIN BRIGHTENER

night cream

## Product Information

Route of Administration TOPICAL

## Other Ingredients

| Ingredient Kind | Ingredient Name                                    | Quantity |
|-----------------|--|----------|
| INGR            | EDETATE DISODIUM (UNII: 7FLD91C86K)                |          |
| INGR            | PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A) |          |
| INGR            | TROLAMINE SALICYLATE (UNII: H8O4040BHD)            |          |
| INGR            | SODIUM LAURYL SULFATE (UNII: 368GB5141J)           |          |
| INGR            | CETYL ALCOHOL (UNII: 936JST6JCN)                   |          |
| INGR            | LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)   |          |

|      |   |  |
|------|---|--|
| INGR | .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |  |
| INGR | ASCORBIC ACID (UNII: PQ6CK8PD0R)              |  |
| INGR | SODIUM METABISULFITE (UNII: 4VON5FNS3C)       |  |
| INGR | METHYL PARABEN (UNII: A2B8C7H9T)              |  |
| INGR | PROPYL PARABEN (UNII: Z8IX2SC1OH)             |  |
| INGR | BUTYLATED HYDROXY TOLUENE (UNII: 1P9D0Z171K)  |  |
| INGR | PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)        |  |
| INGR | GLYCERIN (UNII: PDC6A3C0OX)                   |  |
| INGR | WATER (UNII: 059QF0K00R)                      |  |
| INGR | ARBUTIN (UNII: C5INA23HXF)                    |  |

### Product Characteristics

|       |       |        |
|-------|-------|--------|
| color | WHITE | C48325 |
|-------|-------|--------|

### Packaging

| # | Item Code | Package Description  | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| COSMETIC           |  | 01/01/2004           |                    |

### Part 3 of 5

## OBAGI -C FX SYSTEM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

### Product Information

|                         |               |
|-------------------------|---------------|
| Item Code (Source)      | NDC:62032-142 |
| Route of Administration | TOPICAL       |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE        | 100 mg in 1 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE        | 50 mg in 1 g  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 165 mg in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R)                                  |          |
| GLYCERIN (UNII: PDC6A3C0OX)                               |          |
| Hydroxyacetophenone (UNII: G1L3HT4CMH)                    |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                            |          |
| Sodium Chloride (UNII: 451W47IQ8X)                        |          |
| Sodium Hydroxide (UNII: 55X04QC32I)                       |          |
| Octyldodecyl Neopentanoate (UNII: X8725R883T)             |          |
| Triethoxycaprylylsilane (UNII: LDC331P08E)                |          |
| C15-19 Alkane (UNII: C187N1M01)                           |          |
| Disteardimonium Hectorite (UNII: X687XDK09L)              |          |
| POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)         |          |
| Sorbitan Olivatate (UNII: MDL271E3GR)                     |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                            |          |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G)                         |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                       |          |
| Candelilla Wax (UNII: WL0328HX19)                         |          |
| Yellow Wax (UNII: 2ZA36H0S2V)                             |          |
| POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69) |          |
| Silicon Dioxide (UNII: ETJ7Z6XBU4)                        |          |

### Product Characteristics

|          |       |              |  |
|----------|-------|--------------|--|
| Color    | WHITE | Score        |  |
| Shape    |       | Size         |  |
| Flavor   |       | Imprint Code |  |
| Contains |       |              |  |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62032-142-11 | 85 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 FINAL | part352                                  | 12/02/2019           |                    |

## Part 4 of 5

### OBAGI -C FX SYSTEM C-CLEANSING

cleansing (cold creams, cleansing lotions, liquids, and pads) gel

### Product Information

Route of Administration TOPICAL



## Other Ingredients

| Ingredient Kind | Ingredient Name  | Quantity |
|-----------------|--|----------|
| INGR            | <b>WATER</b> (UNII: 059QF0KO0R)                          |          |
| INGR            | <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                       |          |
| INGR            | <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                 |          |
| INGR            | <b>ETHYLPARABEN</b> (UNII: 14255EXE39)                   |          |
| INGR            | <b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)                |          |
| INGR            | <b>BUTYLPARABEN</b> (UNII: 3QP1U3FV8)                    |          |
| INGR            | <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                  |          |
| INGR            | <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                  |          |
| INGR            | <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)          |          |
| INGR            | <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)                  |          |
| INGR            | <b>SODIUM LAUROYL OAT AMINO ACIDS</b> (UNII: FSW2K9B9N5) |          |
| INGR            | <b>COCAMIDO PROPYL BETAINE</b> (UNII: 5OCF3O11KX)        |          |
| INGR            | <b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)       |          |
| INGR            | <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                 |          |
| INGR            | <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                |          |
| INGR            | <b>ALFALFA</b> (UNII: DJO934BRBD)                        |          |
| INGR            | <b>CHAMOMILE</b> (UNII: FGL3685T2X)                      |          |
| INGR            | <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                    |          |
| INGR            | <b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)             |          |
| INGR            | <b>BORAGE</b> (UNII: PB618V0K2W)                         |          |

## Product Characteristics

|       |        |        |
|-------|--------|--------|
| color | ORANGE | C48331 |
|-------|--------|--------|

## Packaging

| # | Item Code | Package Description  | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| COSMETIC           |  | 01/01/2004           |                    |

## Part 5 of 5

### OBAGI -C FX SYSTEM C-BALANCING TONER

cleansing (cold creams, cleansing lotions, liquids, and pads) liquid

**Product Information****Route of Administration**

TOPICAL

**Other Ingredients**

| Ingredient Kind | Ingredient Name                                       | Quantity |
|-----------------|---|----------|
| INGR            | WATER (UNII: 059QF0K00R)                              |          |
| INGR            | METHYL PARABEN (UNII: A2I8C7HI9T)                     |          |
| INGR            | PHENOXYETHANOL (UNII: HIE492ZZ3T)                     |          |
| INGR            | PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                   |          |
| INGR            | ALOE VERA LEAF (UNII: ZY81Z83H0X)                     |          |
| INGR            | HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)     |          |
| INGR            | BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)              |          |
| INGR            | SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)     |          |
| INGR            | POLYQUATERNIUM-10 (400 MPAS At 2%) (UNII: HB1401PQFS) |          |
| INGR            | PANTHENOL (UNII: WV9CM0O67Z)                          |          |

**Packaging**

| # | Item Code | Package Description  | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| COSMETIC           |  | 01/01/2009           |                    |

**Marketing Information**

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER |  | 12/02/2019           |                    |

**Labeler** - Obagi Cosmeceuticals LLC (790553353)**Establishment**

| Name  | Address | ID/FEI    | Business Operations   |
|---|---------|-----------|---|
| Universal Packaging Systems, Inc. DBA: PakLab |         | 790530976 | MANUFACTURE(62032-536) , LABEL(62032-536) , PACK(62032-536) |

**Establishment**

| Name                     | Address | ID/FEI    | Business Operations    |
|--------------------------|---------|-----------|------------------------|
| Swiss American CDMO, LLC |         | 080170933 | MANUFACTURE(62032-536) |

**Establishment**

| Name                             | Address | ID/FEI    | Business Operations                    |
|----------------------------------|---------|-----------|--|
| Bay Cities Container Corporation |         | 066229618 | RELABEL(62032-536) , REPACK(62032-536) |

Revised: 10/2019

Obagi Cosmeceuticals LLC