

**OBAGI NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL-  
hydroquinone, homosalate, octisalate, 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 Nu-Derm® System Normal-Oily Skin Transformation Trial**

***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 Olivatate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

**Questions or comments?**

**1.800.636.7546** Monday–Friday 9 a.m.–4 p.m. PST

**Distributed by** Obagi Cosmeceuticals LLC, Long Beach, CA 90806

**PRINCIPAL DISPLAY PANEL - Kit Carton**

OBAGI®  
MEDICAL

OBAGI NU-DERM® SYSTEM

A total systematic approach to skin care. Addresses signs of skin aging, gently exfoliates to promote cell turnover and suppresses melanocyte activity to reduce hyperpigmentation.

NORMAL OILY

Skin Transformation Trial Kit

OBAGI<sup>®</sup>  
MEDICAL

## OBAGI NU-DERM<sup>®</sup> SYSTEM

A total systematic approach to skin care. Addresses signs of skin aging, gently exfoliates to promote cell turnover and suppresses melanocyte activity to reduce hyperpigmentation.



NORMAL OILY

Skin Transformation Trial Kit

Sun Shield Matte Broad Spectrum SPF 50 | Netwt. 1 oz. (28 g)

### Drug Facts

| Active ingredients | Purpose   |
|--------------------|-----------|
| 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

### Drug Facts (continued)

#### 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 Olivrate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

#### Questions or comments?

1.800.636.7546 Monday–Friday 9 a.m.–4 p.m. PST

Store at controlled room temperature 15°–25°C (59°–77°F).

FOR ALL PRODUCTS

Warnings: **Avoid getting into eyes.** If product gets into the eyes, thoroughly rinse with water. **For external use only. Keep out of reach of children.**

Distributed by Obagi Cosmetics, LLC, Long Beach, CA 90806

**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



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Made in USA with US and imported components. 856810222-1

### Foaming Gel | 2 fl. oz. (59 mL)

**Directions:** Use twice daily, morning and evening. Wet hands and face. Work a small amount of cleanser into lather and massage onto skin with a gentle circular motion. Rinse with lukewarm water and gently pat dry.

**Ingredients:** Water (Aqua), Sodium Laureth Sulfate, Sodium Lauryl Oat Amino Acids, Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Glycerin, Medicago Sativa (Alfalfa) Extract, Borago Officinalis Extract, Chamomilla Recutita (Matricaria) Flower Extract, Sodium Chloride, Xanthan Gum, Saponins, Phenoxylethanol, Methylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Fragrance (Parfum), Red 33 (CI 17200), Yellow 5 (CI 19140)

### Toner | 2 fl. oz. (59 mL)

**Directions:** Use daily, in the morning and evening after cleansing. Shake before use. Saturate a cotton pad and gently wipe over entire face. Do not rinse.

**Ingredients:** Water (Aqua), Hamamelis Virginiana (Witch Hazel) Water, Aloe Barbadensis Leaf Juice, Potassium Alum, Sodium PCA, Panthenol, DMDM Hydantoin, Polysorbate 80, Allantoin, Glycerin, Salvia Officinalis (Sage) Leaf Extract, Borago Officinalis Extract, Calendula Officinalis Flower Extract, Saponins, Isopropylmyl Butylcarbamate, Fragrance (Parfum), Blue 1 (CI 42090)

### Exfolderm® Forte [Exfoliation Enhancer] | Net wt. 1 oz. (28 g)

**Directions:** Use daily, in the morning. Squeeze a small amount (approximately 1-2 pea-size drops) onto your hands. Using your fingertips, apply evenly to the entire face. Massage until completely absorbed.

**Sunburn Alert:** This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

**Ingredients:** Water (Aqua), Triethanolamine, Glycerin, Glycolic Acid, Caprylic/Capric Triglyceride, Lactic Acid, Cetyl Alcohol, Polysorbate 60, Cetyl Alcohol, Emu Oil, Stearic Acid, Stearyl Alcohol, Dimethicone, Methylparaben, Propylparaben, Saponins

### Clear [Skin Bleaching and Corrector Cream]

Hydroquinone USP, 4% Rx only NDC 62032-101-36  
Net wt. 2 oz. (57 g)

**Indications and usage:** The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation.

**Dosage and administration:** Use daily, in the morning and evening. Squeeze a small amount (approximately 1-2 pea-size amounts) onto your hand. Apply evenly to the entire face, extending to the hairline, over the ears, and ending with a feathering motion, or as directed by your physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring.

**Warnings:** Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, patient should rinse thoroughly with water and contact a physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity. ▶

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Each gram of Obagi Nu-Derm® Clear contains:

Active ingredient: Hydroquinone USP, 4% (40 mg/g)

Inactive ingredients: Water (Aqua), Cetyl Alcohol, Glycerin, Sodium Lauryl Sulfate, Stearyl Alcohol, Lactic Acid, Tocopheryl Acetate, Ascorbic Acid, Sodium Metabisulfite, Disodium EDTA, Methylparaben, BHT, Propylparaben, Saponins, Butylparaben

See enclosed Package Insert for prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

### Blender® [Skin Lightener and Blending Cream]

Hydroquinone USP, 4% Rx only NDC 62032-100-10  
Net wt. 2 oz. (57 g)

**Indications and usage:** The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation.

**Dosage and administration:** Use daily, in the evening. Squeeze a small amount (approximately 1-2 pea-size drops) onto your hand. Apply evenly to the entire face, or as directed by your skin care physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring.

**Warnings:** Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, patient should rinse thoroughly with water and contact a physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Each gram of Obagi Nu-Derm Blender contains:

Active ingredient: Hydroquinone USP, 4% (40 mg/g)

Inactive ingredients: Water (Aqua), Glycerin, Cetyl Alcohol, PPG-2 Myristyl Ether Propionate, Sodium Lauryl Sulfate, TEA-Salicylate, Lactic Acid, Phenyl Trimethicone, Tocopheryl Acetate, Sodium Metabisulfite, Ascorbic Acid, Methylparaben, Disodium EDTA, Propylparaben, Saponins, BHT

See enclosed Package Insert for prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

## Foaming Gel | AM+PM

A gel-based facial cleanser that transforms into a light and airy foam for a gentle daily cleansing experience. Formulated specially for normal to oily skin, the Obagi Nu-Derm® Foaming Gel is designed to cleanse pores and remove makeup, dirt, and excess oil, leaving your skin feeling completely clean and ready for the next step of your skin care regimen.

## Toner | AM+PM

An essential step in your daily skin care routine, this alcohol-free, non-drying toner helps adjust your skin's pH.



Use after cleansing to remove impurities and dead skin while preparing the skin for hydration or appropriate products.

**Exfoderm® Forte (Exfoliation Enhancer) | AM**

A lightweight lotion that exfoliates the top layer of skin, removing dull, old skin while revealing new skin for a brighter complexion. Specifically developed for normal to oily skin that may need more exfoliation, this formula contains alpha-hydroxy acids (glycolic acid, lactic acid) to help smooth roughness and reveal your skin's radiance.

**Clear (Skin Bleaching and Corrector Cream) | AM+PM**

Hydroquinone USP, 4% Rx Only, NDC 62032-101-36

Dark spots may appear on the surface of your skin, but they actually start deep within the skin's layers. This effective formula absorbs into the layers of your skin to deliver prescription-strength hydroquinone, helping to correct dark spots for a healthier-looking, more even complexion.

**Blender® (Skin Lightener and Blending Cream) | PM**

Hydroquinone USP, 4% Rx Only, NDC 62032-100-10

A unique formula containing prescription-strength hydroquinone for the gradual lightening of sun spots or age spots and other types of hyperpigmentation (discoloration). Specially formulated to optimize the delivery of product ingredients in the Obagi Nu-Derm® System, this skin lightener helps reduce signs of aging by correcting uneven skin tone.

**Sun Shield Matte Broad Spectrum SPF 50 | AM**

Obagi Nu-Derm® sunscreen combines UVB absorption and UVA protection in an elegant, matte finish that is non-comedogenic and dermatologist tested. Sheer and fragrance free for all skin types.

OBAGI  
MEDICAL

**OBAGI NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL**

hydroquinone, homosalate, octisalate, zinc oxide kit

| Product Information |                   |                         |                        |                    |
|---------------------|-------------------|-------------------------|------------------------|--------------------|
| Product Type        |                   | HUMAN PRESCRIPTION DRUG | Item Code (Source)     | NDC:62032-914      |
|                     |                   |                         |                        |                    |
| Packaging           |                   |                         |                        |                    |
| #                   | Item Code         | Package Description     | Marketing Start Date   | Marketing End Date |
| 1                   | NDC:62032-914-01  | 1 in 1 KIT              | 06/25/2021             |                    |
|                     |                   |                         |                        |                    |
| Quantity of Parts   |                   |                         |                        |                    |
| Part #              | Package Quantity  |                         | Total Product Quantity |                    |
| Part 1              | 1 BOTTLE, PLASTIC |                         | 59 mL                  |                    |
| Part 2              | 1 BOTTLE, PLASTIC |                         | 59 mL                  |                    |
| Part 3              | 1 BOTTLE, PLASTIC |                         | 57 g                   |                    |
| Part 4              | 1 BOTTLE, PLASTIC |                         | 28 g                   |                    |
| Part 5              | 1 BOTTLE, PLASTIC |                         | 28 g                   |                    |
| Part 6              | 1 TUBE            |                         | 28 g                   |                    |
|                     |                   |                         |                        |                    |
| Part 1 of 6         |                   |                         |                        |                    |

**NU-DERM FOAMING**

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] gel

**Product Information**

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

**Other Ingredients**

| Ingredient Kind | Ingredient Name                                          | Quantity |
|-----------------|----------------------------------------------------------|----------|
| INGR            | <b>WATER</b> (UNII: 059QF0KO0R)                          |          |
| INGR            | <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                 |          |
| INGR            | <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                  |          |
| INGR            | <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                  |          |
| INGR            | <b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)                   |          |
| INGR            | <b>ETHYLPARABEN</b> (UNII: 14255EXE39)                   |          |
| INGR            | <b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)                |          |
| INGR            | <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)          |          |
| INGR            | <b>SODIUM LAUROYL OAT AMINO ACIDS</b> (UNII: FSW2K9B9N5) |          |
| INGR            | <b>COCAMIDOPROPYL 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>MEDICAGO SATIVA WHOLE</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>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)        |          |

**Packaging**

| # | Item Code | Package Description                                           | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------------------------------------------------|----------------------|--------------------|
| 1 |           | 59 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           |                                          | 01/01/1988           |                    |

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

| 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>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V) |          |
| INGR              | <b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2) |          |
| INGR              | <b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)                 |          |
| INGR              | <b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)    |          |
| INGR              | <b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)                 |          |
| INGR              | <b>PANTHENOL</b> (UNII: WW9CM0O67Z)                      |          |
| INGR              | <b>SAGE</b> (UNII: 065C5D077J)                           |          |
| INGR              | <b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)   |          |
| INGR              | <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                 |          |
| INGR              | <b>ALLANTOIN</b> (UNII: 344S277G0Z)                      |          |
| INGR              | <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                 |          |
| INGR              | <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)            |          |
| INGR              | <b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)        |          |

| Packaging |           |                                                               |                      |                    |
|-----------|-----------|---------------------------------------------------------------|----------------------|--------------------|
| #         | Item Code | Package Description                                           | Marketing Start Date | Marketing End Date |
| 1         |           | 59 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              |                                          | 01/01/1988           |                    |

| Part 3 of 6                                                             |
|-------------------------------------------------------------------------|
| <b>NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR</b><br>hydroquinone cream |

| Product Information |
|---------------------|
|---------------------|

|                                                                  |                                          |                                                              |                      |                    |
|------------------------------------------------------------------|------------------------------------------|--------------------------------------------------------------|----------------------|--------------------|
| Item Code (Source)                                               | NDC:62032-101                            |                                                              |                      |                    |
| Route of Administration                                          | TOPICAL                                  |                                                              |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Active Ingredient/Active Moiety                                  |                                          |                                                              |                      |                    |
| Ingredient Name                                                  |                                          | Basis of Strength                                            | Strength             |                    |
| HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE) |                                          | HYDROQUINONE                                                 | 40 mg in 1 g         |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Inactive Ingredients                                             |                                          |                                                              |                      |                    |
| Ingredient Name                                                  |                                          | Strength                                                     |                      |                    |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                              |                                          |                                                              |                      |                    |
| BUTYLPARABEN (UNII: 3QPI1U3FV8)                                  |                                          |                                                              |                      |                    |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y)                               |                                          |                                                              |                      |                    |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                         |                                          |                                                              |                      |                    |
| CETYL ALCOHOL (UNII: 936JST6JCN)                                 |                                          |                                                              |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                                      |                                          |                                                              |                      |                    |
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)                 |                                          |                                                              |                      |                    |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                    |                                          |                                                              |                      |                    |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)                                 |                                          |                                                              |                      |                    |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)                          |                                          |                                                              |                      |                    |
| WATER (UNII: 059QF0KO0R)                                         |                                          |                                                              |                      |                    |
| METHYLPARABEN (UNII: A2I8C7HI9T)                                 |                                          |                                                              |                      |                    |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                                 |                                          |                                                              |                      |                    |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                      |                                          |                                                              |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Product Characteristics                                          |                                          |                                                              |                      |                    |
| Color                                                            | white                                    | Score                                                        |                      |                    |
| Shape                                                            |                                          | Size                                                         |                      |                    |
| Flavor                                                           |                                          | Imprint Code                                                 |                      |                    |
| Contains                                                         |                                          |                                                              |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Packaging                                                        |                                          |                                                              |                      |                    |
| #                                                                | Item Code                                | Package Description                                          | Marketing Start Date | Marketing End Date |
| 1                                                                | NDC:62032-101-36                         | 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 |
| unapproved drug other                                            |                                          |                                                              | 01/01/1988           |                    |
|                                                                  |                                          |                                                              |                      |                    |



Part 4 of 6

NU-DERM EXFODERM FORTE EXFOLIATION ENHANCER

face and neck (excluding shaving preparations), leave-on [skin care preparations (creams, lotions, powder, and sprays)] lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

| Ingredient Kind | Ingredient Name                                         | Quantity |
|-----------------|---------------------------------------------------------|----------|
| INGR            | <b>WATER</b> (UNII: 059QF0KO0R)                         |          |
| INGR            | <b>GLYCERIN</b> (UNII: PDC6A3C00X)                      |          |
| INGR            | <b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)      |          |
| INGR            | <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                 |          |
| INGR            | <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                 |          |
| INGR            | <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)                |          |
| INGR            | <b>TROLAMINE</b> (UNII: 9O3K93S3TK)                     |          |
| INGR            | <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)    |          |
| INGR            | <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)           |          |
| INGR            | <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                 |          |
| INGR            | <b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT) |          |
| INGR            | <b>EMU OIL</b> (UNII: 344821WD61)                       |          |
| INGR            | <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                  |          |
| INGR            | <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)               |          |
| INGR            | <b>GLYCOLIC ACID</b> (UNII: 0WT12SX38S)                 |          |

Packaging

| # | Item Code | Package Description                                          | Marketing Start Date | Marketing End Date |
|---|-----------|--------------------------------------------------------------|----------------------|--------------------|
| 1 |           | 28 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           |                                          | 01/01/1988           |                    |

Part 5 of 6

NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

|                                                                  |                                          |                                                              |                      |                    |
|------------------------------------------------------------------|------------------------------------------|--------------------------------------------------------------|----------------------|--------------------|
| Product Information                                              |                                          |                                                              |                      |                    |
| Route of Administration                                          |                                          | TOPICAL                                                      |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Active Ingredient/Active Moiety                                  |                                          |                                                              |                      |                    |
| Ingredient Name                                                  |                                          | Basis of Strength                                            | Strength             |                    |
| HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE) |                                          | HYDROQUINONE                                                 | 40 mg in 1 g         |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Inactive Ingredients                                             |                                          |                                                              |                      |                    |
| Ingredient Name                                                  |                                          |                                                              | Strength             |                    |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                              |                                          |                                                              |                      |                    |
| PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)               |                                          |                                                              |                      |                    |
| TROLAMINE SALICYLATE (UNII: H8O4040BHD)                          |                                          |                                                              |                      |                    |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                         |                                          |                                                              |                      |                    |
| CETYL ALCOHOL (UNII: 936JST6JCN)                                 |                                          |                                                              |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                                      |                                          |                                                              |                      |                    |
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)                 |                                          |                                                              |                      |                    |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                    |                                          |                                                              |                      |                    |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)                                 |                                          |                                                              |                      |                    |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)                          |                                          |                                                              |                      |                    |
| WATER (UNII: 059QF0KO0R)                                         |                                          |                                                              |                      |                    |
| METHYLPARABEN (UNII: A2I8C7HI9T)                                 |                                          |                                                              |                      |                    |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                                 |                                          |                                                              |                      |                    |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                      |                                          |                                                              |                      |                    |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)                           |                                          |                                                              |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Product Characteristics                                          |                                          |                                                              |                      |                    |
| Color                                                            | white                                    | Score                                                        |                      |                    |
| Shape                                                            |                                          | Size                                                         |                      |                    |
| Flavor                                                           |                                          | Imprint Code                                                 |                      |                    |
| Contains                                                         |                                          |                                                              |                      |                    |
|                                                                  |                                          |                                                              |                      |                    |
| Packaging                                                        |                                          |                                                              |                      |                    |
| #                                                                | Item Code                                | Package Description                                          | Marketing Start Date | Marketing End Date |
| 1                                                                |                                          | 28 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 |
| unapproved drug<br>other                                         |                                          |                                                              | 01/01/1988           |                    |

Part 6 of 6

SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

|                         |               |
|-------------------------|---------------|
| Item Code (Source)      | NDC:62032-140 |
| 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: CI87N1IM01)                          |          |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)              |          |
| POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)             |          |
| SORBITAN OLIVATE (UNII: MDL271E3GR)                       |          |
| DIMETHICONE, UNSPECIFIED (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  |  |

|                              |                                                 |                                                   |                             |
|------------------------------|-------------------------------------------------|---------------------------------------------------|-----------------------------|
| <b>Flavor</b>                |                                                 | <b>Imprint Code</b>                               |                             |
| <b>Contains</b>              |                                                 |                                                   |                             |
|                              |                                                 |                                                   |                             |
| <b>Packaging</b>             |                                                 |                                                   |                             |
| <b>#</b>                     | <b>Item Code</b>                                | <b>Package Description</b>                        | <b>Marketing Start Date</b> |
| 1                            | NDC:62032-140-05                                | 28 g in 1 TUBE; Type 0: Not a Combination Product |                             |
|                              |                                                 |                                                   |                             |
| <b>Marketing Information</b> |                                                 |                                                   |                             |
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                       | <b>Marketing End Date</b>   |
| OTC MONOGRAPH DRUG           | M020                                            | 12/02/2019                                        |                             |
|                              |                                                 |                                                   |                             |
| <b>Marketing Information</b> |                                                 |                                                   |                             |
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                       | <b>Marketing End Date</b>   |
| UNAPPROVED DRUG OTHER        |                                                 | 12/02/2019                                        |                             |

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

**Registrant** - G. S. Cosmeceutical USA, Inc. (017014734)

| Establishment                 |         |           |                        |
|-------------------------------|---------|-----------|------------------------|
| Name                          | Address | ID/FEI    | Business Operations    |
| G. S. Cosmeceutical USA, Inc. |         | 017014734 | MANUFACTURE(62032-914) |

| Establishment            |         |           |                        |
|--------------------------|---------|-----------|------------------------|
| Name                     | Address | ID/FEI    | Business Operations    |
| Swiss American CDMO, LLC |         | 080170933 | MANUFACTURE(62032-914) |

| Establishment                    |         |           |                                    |
|----------------------------------|---------|-----------|------------------------------------|
| Name                             | Address | ID/FEI    | Business Operations                |
| Bay Cities Container Corporation |         | 118417470 | PACK(62032-914) , LABEL(62032-914) |