**NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL- hydroquinone, octinoxate, 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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**NU-DERM® SYSTEM NORMAL-OILY**
**SKIN TRANSFORMATION TRIAL KIT**

**Foaming Gel (Cleanser) 2 fl. oz. (59 mL.) 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 Nu-Derm Foaming Gel deep-cleans pores and removes makeup, dirt, and excess oil, leaving your skin feeling completely clean and ready for the next step of your skin care regimen.

**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.

**Warnings**

Avoid getting into eyes. **For external use only.**

**Keep out of reach of children.**

**Ingredients**

water (aqua), sodium laureth sulfate, sodium lauroyl oat amino acids, cocamidopropyl betaine, aloe barbadensis leaf juice (aloe barbadensis), medicago sativa (alfalfa) extract, borago officinalis extract, chamomilla recutita (matricaria) flower extract (chamomilla recutita extract), glycerin, sodium chloride, xanthan gum, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

**Toner 2 fl. oz. (59 mL.) AM+PM**

An essential step in your daily skin care routine, this alcohol-free, non-drying toner helps adjust your skin's pH for increased penetration of product ingredients. Use after cleansing to remove impurities and dead skin cells and to prepare the skin for hydration or appropriate products.

**Directions**

Use daily, in the morning and evening after cleansing. Saturate a cotton pad and gently wipe over entire face. Do not rinse.

**Warnings**

Avoid getting into eyes. **For external use only.**

**Keep out of reach of children.**

**Ingredients**

water (aqua), hamamelis virginiana (witch hazel) water, aloe barbadensis leaf juice (aloe barbadensis), potassium alum, sodium PCA, panthenol, DMDM hydantoin, polysorbate 80, allantoin, glycerin, salvia officinalis (sage) leaf extract (salvia officinalis), borago officinalis extract, calendula officinalis flower extract (calendula officinalis), saponins, iodopropynyl butylcarbamate, fragrance (parfum), blue 1 (CI 42090)

**Clear (Skin Bleaching and Corrector Cream) NDC 62032-101-36 Net wt. 2 oz. (57 g.)**
**Hydroquinone USP, 4% Rx Only AM+PM**

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

## Indications and usage

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, 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-sized 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

## Warnings

**Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact 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, 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 full prescribing information.

**Rx ONLY. FOR EXTERNAL USE ONLY.**

**Exfoderm® Forte (Exfoliation Enhancer) Net wt. 1 oz. (28 g.) AM**

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

**Directions**

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

**Warnings**

Avoid getting into eyes. **For external use only.**

**Keep out of reach of children.**

**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, lactic acid, cetearyl alcohol, polysorbate 60, caprylic/capric triglyceride, emu oil (dromiceius oil), stearic acid, cetyl alcohol, stearyl alcohol, dimethicone, saponins, methylparaben, propylparaben

**Blender® (Skin Lightener and Blending Cream) NDC 62032-100-36 Net wt. 1 oz. (28 g.) Hydroquinone USP, 4% Rx Only PM**

A unique formula containing prescription-strength hydroquinone for the gradual lightening of sun spots, age spots, and other types of hyperpigmentation (discoloration). Specially formulated to optimize the delivery of product ingredients in the Nu-Derm System, this skin lightener helps reduce the signs of aging and correct uneven skin tone. May be used with Tretinoin Cream[1] or Refissa[2] as prescribed by a physician.

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1 Tretinoin cream is indicated for topical application in the treatment of acne vulgaris.

2 Refissa [Tretinoin Cream, USP (Emollient) 0.05%] is indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs. REFISSA DOES NOT ELIMINATE WRINKLES, REPAIR SUN-DAMAGED SKIN, REVERSE PHOTOAGING, or RESTORE A MORE YOUTHFUL or YOUNGER DERMAL HISTOLOGIC PATTERN.

**Indications and usage**

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation. Specially formulated for blending purposes as part of the Obagi Nu-Derm System.

**Dosage and administration**

Use daily, in the evening. Squeeze a small amount (approximately 1-2 pea-sized 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

**Warnings**

**Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact 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, 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 full prescribing information.

**Rx ONLY. FOR EXTERNAL USE ONLY.**

**Travel Bag and Patient Insruction Guide**

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

Blender, Exfoderm, Nu-Derm, Obagi and the Obagi logo are registered treademarks of OMP, Inc.

Refissa is a registered trademark of Spear Pharmaceuticals, Inc.
Distributed by OMP, Inc., Long Beach, CA 90806


OBAGI.COM Made in USA 41706410Z 7064

**Sun Shield Matte Broad Spectrum SPF 50 Net wt. 1 oz. (28 g.)**

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

***Drug Facts***

| *Active ingredients* | *Purpose* |
|---|---|
| Octinoxate 7.5% | Sunscreen |
| Zinc Oxide 10.5% | 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
- 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 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

**Inactive ingredients**

1,2-hexanediol, caprylyl glycol, ceteareth-20, cetearyl alcohol, chlorphenesin, citric acid, cyclopentasiloxane, dimethicone crosspolymer-3, disodium EDTA, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-10 dimethicone, PEG-40 stearate, pentylene glycol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tocopheryl acetate, tropolone, ubiquinone, water, xanthan gum

**Other information**

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

**Questions or comments?**

**1.800.636.7546**
Monday–Friday 9 a.m.-4 p.m. Pacific Time

**PRINCIPAL DISPLAY PANEL - Kit Carton**

NDC# 62032-515-60

**OBAGI®**
**MEDICAL**

**NU-DERM® SYSTEM**

NORMAL OILY

Skin Transformation Trial Kit

OBAGI MEDICAL

## NU-DERM® SYSTEM

The #1 prescription-strength, physician-dispensed skincare system that transforms cellular functions at all layers of the skin, helping to make skin look and act younger and healthier.

NORMAL OILY

Skin Transformation Trial Kit

### Foaming Gel (Cleanser) 2 fl. oz. (59 mL) AM+PM

A gel-based facial cleanser that transforms into a light and airy foam for a gentle daily cleansing experience. Formulated specifically for normal to oily skin, the NuDerm Foaming Gel deep-cleans pores and removes makeup, dirt, and excess oil, leaving your skin feeling completely clean and ready for the next step of your skin care regimen.

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

**Warnings:** Avoid getting into eyes. **For external use only. Keep out of reach of children.**

**Ingredients:** water (aqua), sodium lauroyl sulfate, sodium lauroyl oat amino acids, cocamidopropyl betaine, aloe barbadensis leaf juice (aloe barbadensis), *Hordeum vulgare* (extract), borago officinalis extract, chamomilla recutita (matricaria) flower extract (chamomile extract), glycerin, sodium chloride, xanthan gum, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

### Toner 2 fl. oz. (59 mL) AM+PM

An essential step in your daily skin care routine. This alcohol-free, refreshing toner helps adjust your skin's pH for increased penetration of product ingredients. Use after cleansing to remove impurities and dead skin cells and to prepare the skin for hydration or appropriate products.

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

**Warnings:** Avoid getting into eyes. **For external use only. Keep out of reach of children.**

**Ingredients:** water (aqua), hamamelis virginiana (witch hazel) water, aloe barbadensis leaf juice (aloe barbadensis), potassium alum, sodium PCA, panthenol, DMDM hydantoin, polysorbate 80, allantoin, glycerin, *rubus idaeus* (raspberry) leaf extract (rubus idaeus), borago officinalis extract, calendula officinalis flower extract (calendula officinalis), saponins, iodopropynyl butylcarbamate, fragrance (parfum), blue 1 (CI 42090)

### Clear (Skin Bleaching and Corrector Cream) NDC 62032-101-36 Net wt. 2 oz. (57 g.) Hydroquinone USP, 4% Rx Only AM+PM

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

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

**Dosage and administration:** Use daily, in the morning and evening, to cover a small amount (approximately 1–2 pea-sized 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

**Warnings: Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure contains 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, cetyl alcohol, glycerin, sodium lauryl sulfate, oleyl alcohol, lactic acid, hexylene glycol, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, propylparaben, saponins, butylparaben

See enclosed Package Insert for full prescribing information.

**Rx ONLY. FOR EXTERNAL USE ONLY.**

### Exfoderm+ Forte (Exfoliation Enhancer) Net wt. 1 oz. (28 g.) AM

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

**Directions:** Use daily, in the morning. Squeeze a small amount (approximately 1–3 pea-sized drops) onto your hands. Using your fingertips, apply evenly to the entire face. Massage until completely absorbed.

**Warnings:** Avoid getting into eyes. **For external use only. Keep out of reach of children.**

**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), methoxydiglycol, glycerin, glycolic acid, lactic acid, cetearyl alcohol, polysorbate 60, caprylic/capric triglyceride, urea (chemical), stearic acid, cetyl alcohol, stearyl alcohol, dimethicone, saponins, methylparaben, propylparaben

### Blender+ (Skin Lightener and Blending Cream) NDC 62032-100-36 Net wt. 1 oz. (28 g.) Hydroquinone USP, 4% Rx Only PM

A unique formula containing prescription-strength hydroquinone for the gradual lightening of sun spots, age spots, and other types of hyperpigmentation (discoloration). Specially formulated to optimize the delivery of product ingredients to the Nu-Derm System, this skin lightener helps reduce the signs of aging and correct uneven skin tone. May be used with Tretinoin Cream* or Refissa† as prescribed by a physician.

**Instructions and usage:** The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation. Specially formulated for blending purposes as part of the Obagi Nu-Derm System.

**Dosage and administration:** Use daily, in the evening. Squeeze a small amount (approximately 1–2 pea-sized 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

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

**Rx ONLY. FOR EXTERNAL USE ONLY.**

* Tretinoin cream is indicated for topical application in the treatment of acne vulgaris.

† Refissa (Tretinoin Cream, USP (Emollient) 0.05%) is indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and lentiginous appearance of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs. REFISSA DOES NOT ELIMINATE WRINKLES, REPAIR SUN-DAMAGED SKIN, REVERSE PHOTOAGING, OR RESTORE A MORE YOUTHFUL OR YOUNGER DERMAL HISTOLOGIC PATTERN.

### Travel Bag and Patient Instruction Guide

### Sun Shield Matte Broad Spectrum SPF 50 Net wt. 1 oz. (28 g.)

This sunscreen combines UVB absorption and UVA protection in an elegant, matte finish that is non-comedogenic, allergy tested, and dermatologist tested. Clean, PABA free, and fragrance free for all skin types.

#### Drug Facts

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.5% | Sunscreen |
| Zinc Oxide 10.8% | 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
- 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 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

**Inactive Ingredients**

1,2-hexanediol, caprylyl glycol, ceteareth-20, cetearyl alcohol, cithrenoveresin, citric acid, cyclopentasiloxane, dimethicone crosspolymer-3, disodium EDTA, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-10 dimethicone, PEG-40 stearate, pentylene glycol, phenyl trimethicone, polybutene-11, polyvinyl alcohol-60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, squalane, stearyl alcohol, tetramethylenyl ascorbate, tocopheryl acetate, tripeptide, ubiquinone, water, xanthan gum

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

**Questions or comments?**

1.800.636.7548

Monday–Friday 8 a.m.–4 p.m. Pacific Time

FPO
Barcode Area
62032515 60

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



OBAGI MEDICAL

NU-DERM® SYSTEM

NORMAL OILY

Skin Transformation Trial Kit

NU-DERM® SYSTEM

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NDC # 62032-515-60

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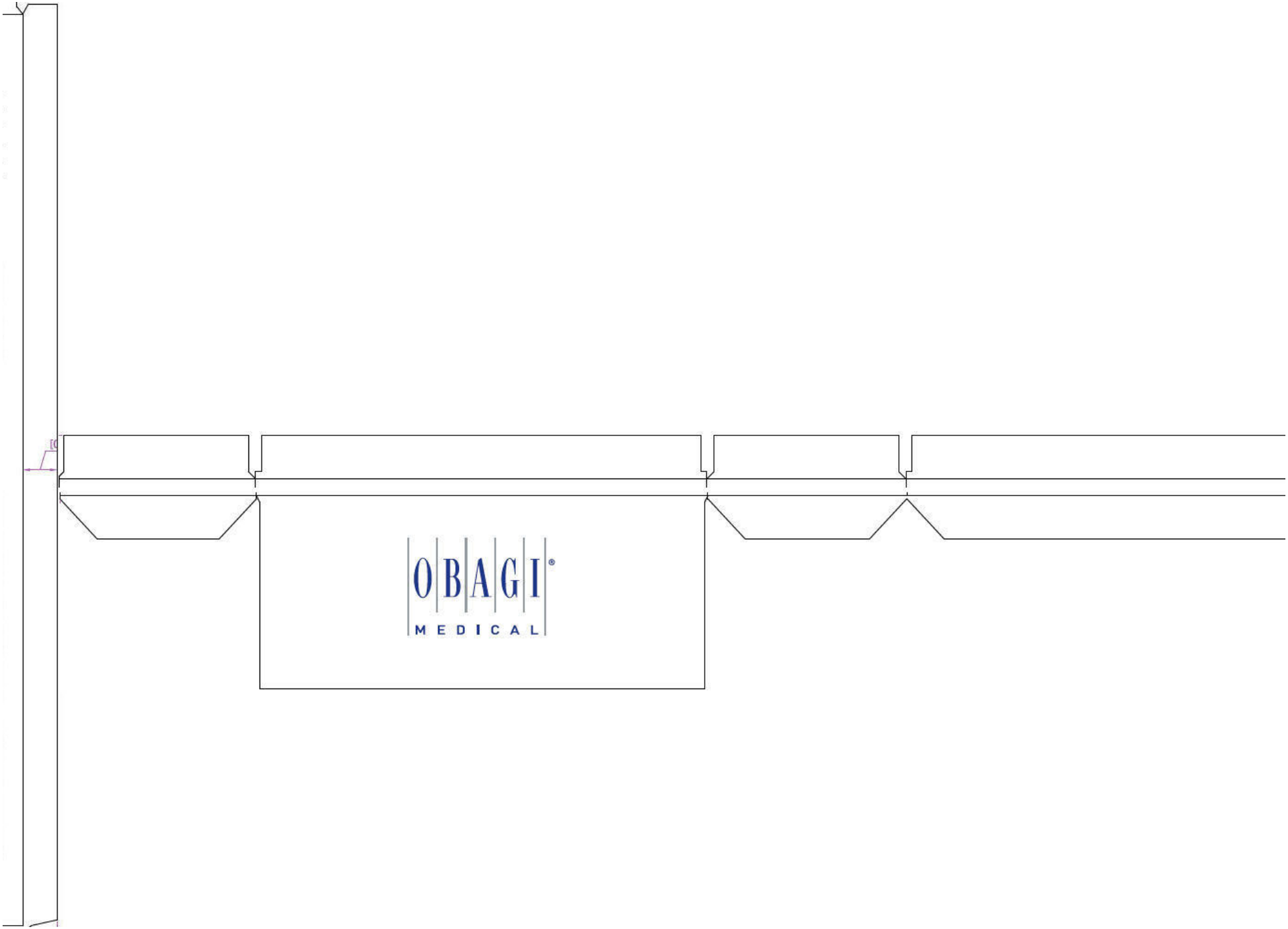
NU-DERM® SYSTEM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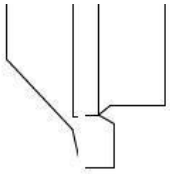
MEDICAL



# NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL

hydroquinone, octinoxate, and zinc oxide kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:62032-515 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:62032-515-60 | 1 in 1 CARTON | 11/07/2012 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE, PLASTIC | 28 g |
| **Part 2** | 1 BOTTLE, PLASTIC | 57 g |
| **Part 3** | 1 TUBE | 28 g |
| **Part 4** | 1 BOTTLE, PLASTIC | 59 mL |
| **Part 5** | 1 BOTTLE, PLASTIC | 59 mL |
| **Part 6** | 1 BOTTLE, PLASTIC | 28 g |

## Part 1 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 other | | 01/01/1988 | |

## Part 2 of 6

## NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

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) | |
| **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** | | 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 3 of 6

## NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

octinoxate and zinc oxide lotion

| Product Information | |
|---|---|
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |

| | | |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 g |
| **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 105 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CYCLOMETHICONE 5** (UNII: 0THT5PCI0R) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **PEG-10 DIMETHICONE (600 CST)** (UNII: 8PR7V1SVM0) | |
| **PENTYLENE GLYCOL** (UNII: 50C1307PZG) | |
| **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| **POLYOXYL 20 CETOSTEARYL ETHER** (UNII: YRC528SWUY) | |
| **PHENYL TRIMETHICONE** (UNII: DR0K5NOJ4R) | |
| **PEG-40 STEARATE** (UNII: ECU18C66Q7) | |
| **SODIUM DIHYDROXYCETYL PHOSPHATE** (UNII: YWI33EV595) | |
| **HYDROGENATED PALM GLYCERIDES** (UNII: YCZ8EM144Q) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **1,2-HEXANEDIOL** (UNII: TR046Y3K1G) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **TROPOLONE** (UNII: 7L6DL16P1T) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **TETRAHEXYLDECYL ASCORBATE** (UNII: 9LBV3F07AZ) | |
| **UBIDECARENONE** (UNII: EJ27X76M46) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **METHYLISOTHIAZOLINONE** (UNII: 229D0E1QFA) | |
| **HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)** (UNII: 86FQE96TZ4) | |
| **SQUALANE** (UNII: GW89575KF9) | |
| **POLYSORBATE 60** (UNII: CAL22UVI4M) | |

## 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 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 | 11/07/2012 | |

## Part 4 of 6

## NU-DERM FOAMING

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

### Product Information

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

### Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|---|---|---|
| INGR | **WATER** (UNII: 059QF0KO0R) | |
| INGR | **GLYCERIN** (UNII: PDC6A3C0OX) | |
| INGR | **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| INGR | **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| INGR | **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| INGR | **BUTYLPARABEN** (UNII: 3QPI1U3FV8) | |
| INGR | **ETHYLPARABEN** (UNII: 14255EXE39) | |
| INGR | **ISOBUTYLPARABEN** (UNII: 0QQJ25X58G) | |
| INGR | **SODIUM LAUROYL OAT AMINO ACIDS** (UNII: FSW2K9B9N5) | |
| INGR | **COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX) | |
| INGR | **SODIUM LAURETH-3 SULFATE** (UNII: BPV390UAP0) | |
| INGR | **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| INGR | **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| INGR | **ALFALFA** (UNII: DJO934BRBD) | |
| INGR | **CHAMOMILE** (UNII: FGL3685T2X) | |
| INGR | **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| INGR | **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |
| INGR | **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | RED | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

### 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 5 of 6

## NU-DERM TONER

face and neck (excluding shaving preparations) liquid

### Product Information

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

### Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|---|---|---|
| INGR | **WATER** (UNII: 059QF0KO0R) | |
| INGR | **GLYCERIN** (UNII: PDC6A3C0OX) | |
| INGR | **SODIUM PYRROLIDONE CARBOXYLATE** (UNII: 469OTG57A2) | |
| INGR | **DMDM HYDANTOIN** (UNII: BYR0546TOW) | |
| INGR | **IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB) | |
| INGR | **POTASSIUM ALUM** (UNII: 1L24V9R23S) | |
| INGR | **PANTHENOL** (UNII: WV9CM0O67Z) | |
| INGR | **SAGE** (UNII: 065C5D077J) | |
| INGR | **CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD) | |
| INGR | **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| INGR | **ALLANTOIN** (UNII: 344S277G0Z) | |
| INGR | **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| INGR | **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| INGR | **HAMAMELIS VIRGINIANA TOP WATER** (UNII: NT00Y05A2V) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

### 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 6 of 6

## NU-DERM EXFODERM FORTE

face and neck (excluding shaving preparations) lotion

### Product Information

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

### Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|---|---|---|
| INGR | **WATER** (UNII: 059QF0KO0R) | |
| INGR | **GLYCERIN** (UNII: PDC6A3C0OX) | |
| INGR | **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| INGR | **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| INGR | **POLYSORBATE 60** (UNII: CAL22UVI4M) | |
| INGR | **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| INGR | **GLYCOLIC ACID** (UNII: 0WT12SX38S) | |
| INGR | **TROLAMINE** (UNII: 9O3K93S3TK) | |
| INGR | **MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U) | |
| INGR | **LACTIC ACID, UNSPECIFIED FORM** (UNII: 33X04XA5AT) | |
| INGR | **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| INGR | **EMU OIL** (UNII: 344821WD61) | |
| INGR | **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| INGR | **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| INGR | **DIMETHICONE** (UNII: 92RU3N3Y1O) | |

### 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 |
|---|---|---|---|
| Cosmetic | | 01/01/1988 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Unapproved drug other | | 11/07/2012 | |

## Labeler - Obagi Cosmeceuticals LLC (790553353)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| MILBAR LABORATORIES | | 195556790 | MANUFACTURE(62032-515) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| PURETEK CORPORATION | | 785961046 | MANUFACTURE(62032-515) , LABEL(62032-515) , PACK(62032-515) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| G.S. COSMECEUTICAL USA, INC. | | 017014734 | MANUFACTURE(62032-515) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Bay Cities Container Corporation | | 066229618 | RELABEL(62032-515) , REPACK(62032-515) |

Revised: 12/2019 Obagi Cosmeceuticals LLC