NU-DERM SYSTEM NORMAL-DRY 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.

NU-DERM® SYSTEM
NORMAL DRY
Skin Transformation Trial Kit

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-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, 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, 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, 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.

Blender® (Skin Lightener and Blending Cream) NDC 62032-100-10 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-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, 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, 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, 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 Instruction Guide

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

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

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

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obagi.com Made in USA 40706311Z 7063

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

This sunscreen combines UVB absorption and UVA protection in an elegant matte finish that is non-comedogenic, hypoallergenic, non-acnegenic, and dermatologist tested. Sheer, PABA free,

Drug Facts

Active ingredients

Octinoxate 7.5%
Zinc Oxide 10.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

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, dimethicone crosspolymer-3, disodium EDTA, glycerin, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-40 stearate, pentylene glycol, phenoxyethanol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, sodium polyacrylate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tropolone, 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# 62032-522-60

OBAGI®
MEDICAL

NU-DERM® SYSTEM

NORMAL DRY

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 DRY

Skin Transformation Trial Kit

Gentle Cleanser 2 fl. oz. (59 mL) AM•PM

A mild facial cleanser that provides gentle yet effective cleansing for normal to dry skin. For skin that's beautifully clear and fresh, the Nu-Derm Gentle Cleanser instantly dissolves excess oil, makeup, and other everyday impurities, without stripping your skin of its natural protective oils, and prepares your skin for the next step in your skin care regimen.

Directions: Use twice daily, morning and evening. Massage a small amount of cleanser and water onto skin. 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), cocamidopropyl betaine, glycerin, sodium lauroyl oat amino acids, aloe barbadensis leaf juice (aloe barbadensis), sodium laureth sulfate, glycereth-7, prunus armeniaca (apricot) kernel oil, panthenol, acrylates/C10-30 alkyl acrylate crosspolymer, ethylhexylglycerin, triethanolamine, salvia officinalis (sage) leaf extract (salvia officinalis), borago officinalis extract, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), yellow 5 (CI 19140)

An essential step in your daily skin care routine, this alcohol-free, nondrying 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, glycerin, glycols, 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 1/4" pea-size amount) 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, 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 melanocyte 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 asthmatics 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® (Skin Smoothing Lotion) Net wt. 1 oz. (28 g) AM

A lightweight lotion that exfoliates the top layer of skin, removing dull, dry skin cells while promoting new skin cells for a brighter complexion. Specifically developed for normal to dry skin, this gentle, skin-enhancing formula contains a plant acid (phytic acid) to help transform the appearance of damaged skin and reveal your skin's radiance.

Directions: Use daily, in the evening. 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.

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

Ingredients: water (aqua), ethoxydiglycol, glycerin, phytic acid, cetearyl alcohol, glyceryl stearate, PEG-100 stearate, canola oil, hydroxatocarpus, magnesium aluminum silicate, potassium cetyl phosphate, cetyl alcohol, bisethylhexyl pyrocatechol, dimethicone, polysorbate 80, PEG-150 stearate, steareth-20, xanthan gum, glycereth-7, tocopheryl acetate, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben

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 restore the signs of aging and correct uneven skin tone. May be used with Tretinoin Cream* or Refissa** as prescribed by a physician.

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-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, 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, 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 melanocyte 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 asthmatics 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 tactile roughness of facial skin in patients who do not achieve such qualities 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

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

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

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

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obagi.com Made in USA 40706311Z 7063

Net wt. 1 oz. (28 g)

This sunscreen combines UVB absorption and UVA protection in an elegant matte finish that is noncomedogenic, hypoallergenic, noncarcinogenic, and dermatologist tested. Oil-free, PABA free, and fragrance free for all skin types.

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 16.6%	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, dimethicone crosspolymer-3, disodium EDTA, glycerin, hydrogenated poly decene, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-40 stearate, pentylene glycol, phenoxyethanol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, sodium polyacrylate, squalane, steryl alcohol, tetrahexyldecyl ascorbate, tromethane, 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

OBAGI MEDICAL

NORMAL DRY

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NORMAL DRY

Skin Transformation Trial Kit

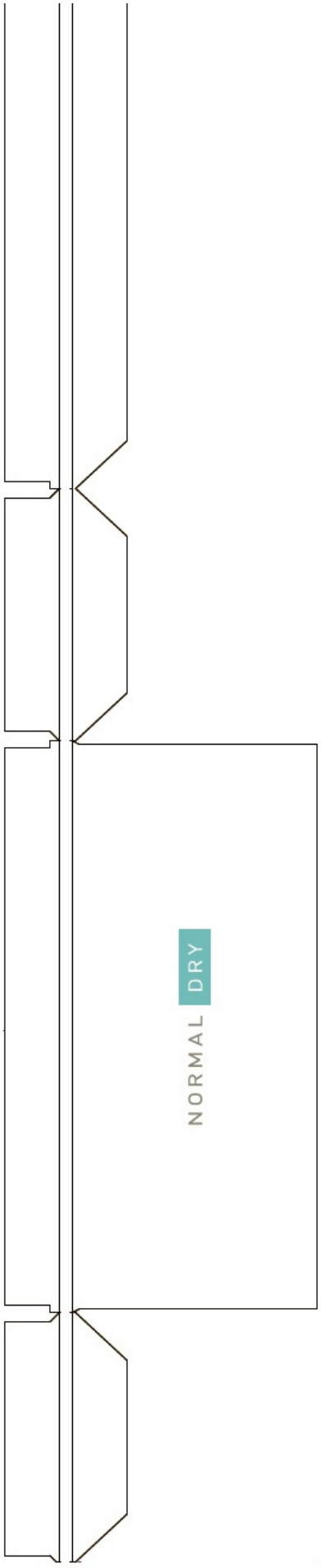
NU-DERM® SYSTEM

OBAGI MEDICAL

NDC# 62032-52260

OBAGI MEDICAL

NORMAL DRY



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

Blender+ (Skin Lightener and Blending Cream) NDC 62032-100-10

Sun Shield Broad Spectrum SPF 50 Matte

NU-DERM SYSTEM NORMAL-DRY SKIN TRANSFORMATION TRIAL

hydroquinone, octinoxate,and zinc oxide kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-522

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62032-522-60	1 in 1 CARTON	04/15/2013	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PLASTIC	28 g
Part 2	1 BOTTLE, PLASTIC	28 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		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 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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TROPOLONE (UNII: 7L6DL16P1T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

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	02/21/2013	

Part 4 of 6

NU-DERM GENTLE CLEANSER

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: 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	**CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)** (UNII: 809Y72KV36)	
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	**GLYCERETH-7** (UNII: 3D2Y91QZ2H)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**TROLAMINE** (UNII: 9O3K93S3TK)	
INGR	**SAGE** (UNII: 065C5D077J)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	
INGR	**APRICOT KERNEL OIL** (UNII: 54JB35T06A)	
INGR	**OLEYL LACTATE** (UNII: B3AWW0N3GM)	

Product Characteristics

Color	YELLOW	**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	**HAMAMELIS VIRGINIANA TOP WATER** (UNII: NT00Y05A2V)	
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)	

Product Characteristics

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

Packaging

Item		Marketing Start	

#	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

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	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**POLYSORBATE 60** (UNII: CAL22UVI4M)	
INGR	**CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S)	
INGR	**STEARETH-20** (UNII: L0Q8IK9E08)	
INGR	**CANOLA OIL** (UNII: 331KBJ17RK)	
INGR	**ISOHEXADECANE** (UNII: 918X1OUF1E)	
INGR	**MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC)	
INGR	**CETYL ALCOHOL** (UNII: 936JST6JCN)	
INGR	**FYTIC ACID** (UNII: 7IGF0S7R8I)	
INGR	**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)	
INGR	**PEG-100 STEARATE** (UNII: YD01N1999R)	
INGR	**DIMETHICONE** (UNII: 92RU3N3Y1O)	
INGR	**PEG-150 STEARATE** (UNII: 7BSG7DF10Q)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**POTASSIUM CETYL PHOSPHATE** (UNII: 03KCY6P7UT)	
INGR	**XANTHAN GUM** (UNII: TTV12P4NEE)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	
INGR	**GLYCERETH-7** (UNII: 3D2Y91QZ2H)	

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		04/15/2013	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-522) , REPACK(62032-522)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-522) , LABEL(62032-522) , PACK(62032-522)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-522)