NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL-
hydroquinone, homosalate, octisalate, and zinc oxide
OBAGI COSMECEUTICAL 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.

OBAGI NU-DERM® SYSTEM

OBAGI NU-DERM®

Rx only

For external use only

DESCRIPTION

Hydroquinone, USP 4% is 1, 4-benzenediol. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.11 g/mol. The chemical structure is in the diagram below.

$C_6H_6O_2$

Each gram of Obagi Nu-Derm® Clear contains:

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

INACTIVES: ascorbic acid, BHT, butylparaben, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, tocopheryl acetate, water (aqua)

Each gram of Obagi Nu-Derm Blender® contains:

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

INACTIVES: ascorbic acid, BHT, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, phenyl trimethicone, PPG-2 myristyl ether propionate, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, TEA-salicylate, tocopheryl acetate, water (aqua)

Each gram of Obagi Nu-Derm® Sunfader® contains:

ACTIVES: Hydroquinone, USP 4% (40mg/g); Octinoxate, USP 7.5%; Oxybenzone, USP

5.5%

INACTIVES: ascorbic acid, BHT, butylparaben, cetyl alcohol, disodium EDTA, glycerin, methylparaben, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, tocopheryl acetate, water (aqua)

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunscreen agents such as those contained in Obagi Nu-Derm Sunfader® and Obagi Nu-Derm® Sun Shield Matte Broad Spectrum SPF 50.

INDICATIONS AND USAGE

For the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS

People with prior history of sensitivity or allergic reaction to this product or any of its ingredients should not use it. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

WARNINGS

Hydroquinone is a skin-bleaching agent, which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this product.

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check within 24 hours. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor. Close patient supervision is recommended.

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.

PRECAUTIONS

(also see WARNINGS):

Treatment should be limited to relatively small areas of the body at one time since some patients experience a transient skin reddening and a mild burning sensation, which does not preclude treatment.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used on pregnant women only when clearly indicated.

NURSING MOTHERS

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

PEDIATRIC USAGE

Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur, in which case the product should be discontinued and the physician notified immediately.

To report SUSPECTED ADVERSE REACTIONS, contact Obagi Cosmeceuticals LLC, at 1-800-636-7546 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

A thin application should be applied once or twice daily or as directed by a 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 reoccurring.

HOW SUPPLIED

Obagi Nu-Derm® Clear is available as follows:
Net wt. 2 oz. (57 g) bottle
NDC 62032-101-36

Obagi Nu-Derm Blender® is available as follows:
Net wt. 2 oz. (57 g) bottle

NDC 62032-100-36

Net wt. 1 oz. (28 g) bottle
NDC 62032-100-10

Obagi Nu-Derm Sunfader® is available as follows:
Net wt. 2 oz. (57 g) bottle
NDC 62032-116-36

Store at controlled room temperature: 15° to 25°C (59° to 77°F). Keep out of direct sunlight.

1-800-636-7546
Manufactured for:
Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

Revised 01/2019
9458404

Obagi Nu-Derm® Clear (Hydroquinone, USP 4%) Skin Bleaching Cream

Obagi Nu-Derm Blender® (Hydroquinone, USP 4%) Skin Bleaching Cream

Obagi Nu-Derm Sunfader® (Hydroquinone, USP 4%; Octinoxate, USP 7.5%; Oxybenzone, USP 5.5%) Skin Bleaching Cream with Sunscreens

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

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
- **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 Olivate, Silica, Polyglyceryl-6 Polyrininoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Questions or comments?

1.800.636.7546

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

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 62032-533-60

OBAGI®
MEDICAL

OBAGI NU-DERM® SYSTEM

NORMAL OILY

Skin Transformation Trial Kit

OBAGI MEDICAL

OBAGI NU-DERM® SYSTEM

The #1 prescription-strength, physician-dispensed skincare 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

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 cleaning experience. Particularly especially 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.

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 pat dry.

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.

Ingredients: water (aqua), cocamidopropyl betaine, sodium lauroyl sarcosinate, sodium benzoyl sulfate, disodium lauryl sulfosuccinate, 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. Use after cleansing to remove impurities and dead skin cells, preparing the skin for hydration or appropriate products.

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.

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.

Ingredients: water (aqua), hamamelis virginiana (witch hazel) water, aloe barbadensis leaf juice, potassium cetyl phosphate, sodium PCA, panthenol, PEG/PPG-17/6 copolymer, polysorbate 80, glycerin, glycine soja (soybean) oil, sodium citrate, borago officinalis extract, calendula officinalis flower extract, saponins, isohexyldecyl behenate, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

Clear (Skin Bleaching and Corrector Cream) NDC 62032-101-34 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 effective formula absorbs into the layers of your skin to deliver prescription-strength hydroquinone, helping to correct the appearance of age or 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 the size of a pea) 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 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 (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 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 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.

Directions: Use daily, in the morning. Squeeze a small amount (approximately 3–6 pea-size drops) onto your hands, taking your fingertips, apply evenly to the entire face. Massage and completely absorbed.

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.

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, cetearyl alcohol, polysorbate 60, wax oil (dimethicone 5), stearic acid, cetyl alcohol, stearyl alcohol, dimethicone, saponins, methylparaben, propylparaben

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 or age spots and other types of hyperpigmentation discoloration's. Specially formulated to optimize the delivery of product ingredients in the Obagi Nu-Derm® System, this skin lightener helps correct uneven skin tone.

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 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 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.

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.

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-sulfolipid, lactic acid, phenyltrimethicone, 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 Enclosed

✆ 1-800-636-7566

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

Made in USA with U.S. and Imported components 9528404

Sun Shield Matte Broad Spectrum SPF 50 Net wt. 3 oz. (85 g) 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.

Drug Facts

Active Ingredients	Purpose
Avobenzone 1.5%	Sunscreen
Octisalate 5%	Sunscreen
Zinc Oxide 14.5%	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°–25°C (59°–77°F)
- protect this product from excessive heat and direct sun

Inactive Ingredients
Water (Aqua), C12-15 Alkyl Benzoate, Isododecane, Hexyldecanol, Polymethylsilsesquioxane, Sorbitan Olivate, Silica, Polyglyceryl-4 Polyhydroxystearate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,3-Butanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Dihydrostearoyl Hexanediol, Polyglyceryl-3 Beeswax, Euphorbia Cerifera (Candelilla) Wax, Beeswax, Dimethicone

Questions or comments?
1-800-636-7566
Monday–Friday 7 a.m.–4 p.m. Pacific Time

OBAGI MEDICAL

NORMAL OILY

OBAGI MEDICAL

NORMAL OILY

Skin Transformation Trial Kit

FRONT PANEL

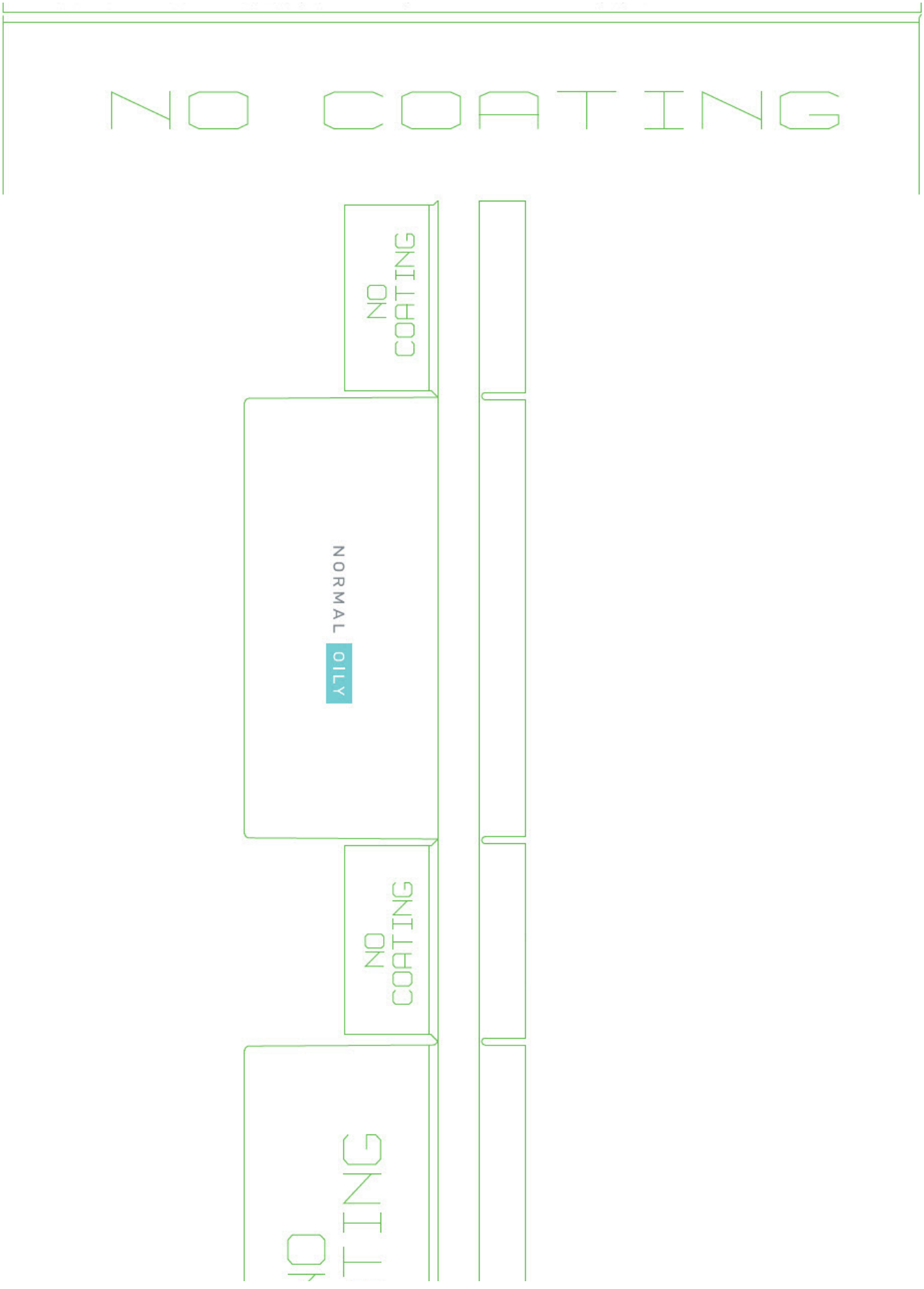
OBAGI NU-DERM® SYSTEM

OBAGI MEDICAL

NDC# 62032-533-60

OBAGI MEDICAL

NORMAL OILY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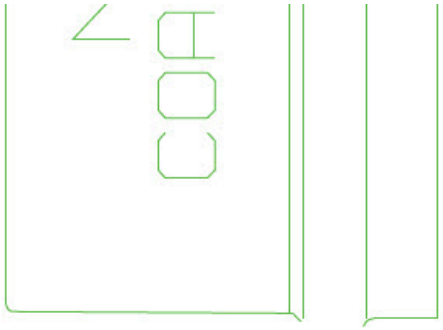

NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION TRIAL

hydroquinone, homosalate, octisalate, and zinc oxide kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-533

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62032-533-60	1 in 1 KIT	12/02/2019	

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	85 g

Part 1 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	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	

INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	
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	**MEDICAGO SATIVA WHOLE** (UNII: DJO934BRBD)	
INGR	**CHAMOMILE** (UNII: FGL3685T2X)	
INGR	**XANTHAN GUM** (UNII: TTV12P4NEE)	
INGR	**D&C RED NO. 33** (UNII: 9DBA0SBB0L)	
INGR	**BORAGO OFFICINALIS SEED** (UNII: 2GXJ790US0)	

Product Characteristics

color	RED	C48326

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 2 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)	
INGR	**BORAGO OFFICINALIS SEED** (UNII: 2GXJ790US0)	

Product Characteristics

color	BLUE	C48333

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

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 4 of 6

NU-DERM EXFODERM FORTE EXFOLIATION ENHANCER

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

Product Characteristics		
color	WHITE	C48325

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 other		01/01/1988	

Part 6 of 6

NU-DERM SUN SHIELD MATTE BROAD SPECTRUM SPF 50 SUNSCREEN

homosalate, octisalate and zinc oxide lotion

Product Information

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 (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Candelilla Wax (UNII: WL0328HX19)	
Yellow Wax (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		85 g in 1 TUBE; Type 0: Not a Combination		

1		Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/02/2019	

Marketing Information

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

Labeler - OBAGI COSMECEUTICAL LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-533) , LABEL(62032-533) , PACK(62032-533)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-533)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-533)