OBAGI MEDICAL - NU-DERM SYSTEM - NORMAL TO DRY - SKIN TRANSFORMATION TRIAL KIT- octinoxate, 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.

OBAGI MEDICAL
NU-DERM® SYSTEM
NORMAL to DRY
Skin Transformation Trial Kit

Gentle Cleanser AM+PM

A mild facial cleanser that provides gentle yet effective cleansing for normal to dry skin. For skin that's beautifully clean and fresh, the 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, oleyl lactate, ethoxydiglycol, triethanolamine, salvia officinalis (sage) leaf extract, borago officinalis extract, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), yellow 5 (CI 19140)

Toner AM+PM

An essential step in your daily skin care routine, this alcohol-free, nondrying toner helps adjust your skin's pH. 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. Shake before use. Saturate a cotton pad and gently wipe over the 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, potassium alum, sodium PCA, panthenol, DMDM hydantoin, polysorbate 80, allantoin, glycerin, salvia officinalis (sage) leaf extract, borago officinalis extract, calendula officinalis flower extract, saponins, iodopropynyl butylcarbamate, fragrance (parfum), blue 1 (CI 42090)

Clear (Skin Bleaching and Corrector Cream) 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 (approximately1-2 pea-size amounts) onto your hand. Apply evenly to the entire face, extending to the hairline, over the ears, and ending with a feathering motion, or as directed by your physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from 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, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, lactic acid, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, propylparaben, saponins, butylparaben

See enclosed Package Insert for prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Exfoderm® (Skin Smoothing Lotion) AM

A lightweight lotion that exfoliates the top layer of skin, removing dull, old skin cells while revealing 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 morning. Squeeze a small amount (approximately 1 to 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, ethoxydiglycol, glycerin, phytic acid, cetearyl alcohol, glyceryl stearate, PEG-100 stearate, magnesium aluminum silicate, canola oil, isohexadecane, potassium cetyl phosphate, cetyl alcohol, bis-diglyceryl polyacyladipate-2, dimethicone, sodium hydroxide, xanthan gum, phenoxyethanol, glycereth-7, polysorbate 60, methylparaben, PEG-150 stearate, steareth-20, tocopheryl acetate, saponins, ethylparaben, butylparaben, isobutylparaben, propylparaben

Blender® (Skin Lightener and Blending Cream) 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 signs of aging by correcting 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.

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 prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY

Sun Shield Broad Spectrum SPF 50 Matte

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

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

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

Questions or comments?

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

Principal Display Panel - Kit Carton

OBAGI®

MEDICAL

OBAGI NU-DERM® SYSTEM

NORMAL DRY

Skin Transformation Trial Kit

OBAGI MEDICAL

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 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 clean 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, oleyl lactate, ethoxydiglycol, triethanolamine, salvia officinalis (sage) leaf extract, borago officinalis extract, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), yellow 5 (CI 19140)

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

An essential step in your daily skin care routine, this alcohol-free, nondrying toner helps adjust your skin's pH. 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. Shake before use. 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, potassium oleth, sodium PCA, panthenol, DMDM hydantoin, polysorbate 80, allantoin, glycerin, salvia officinalis (sage) leaf extract, borago officinalis extract, calendula officinalis flower extract, 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-size amounts) onto your hand. Apply evenly to the entire face, watering 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, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, lactic acid, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, propylparaben, saponins, butylparaben

See enclosed Package Insert for prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Exfoderm® (Skin Smoothing Lotion) Net wt. 1 oz. (28 g) AM

A lightweight lotion that exfoliates the top layer of skin, removing dull, old skin cells while revealing 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 morning. Squeeze a small amount (approximately 1-2 pea-size drops) onto your hands. Using your fingertips, apply evenly to the entire face. Massage until completely absorbed.

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

Ingredients: water, ethoxydiglycol, glycerin, phytic acid, cetearyl alcohol, glyceryl stearate, PEG-100 stearate, magnesium aluminum silicate, canola oil, isohexadecane, potassium cetyl phosphate, cetyl alcohol, bis-diglyceryl polyacyladipate-2, dimethicone, sodium hydroxide, xanthan gum, phenoxyethanol, glycereth-7, polysorbate 60, methylparaben, PEG-150 stearate, steareth-20, tocopheryl acetate, saponins, ethylparaben, butylparaben, isobutylparaben, 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, 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 signs of aging by correcting 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.

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 prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Travel Bag and Patient Instruction Guide Enclosed

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

? 1-800-636-7546

www.obagi.com

9458302

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, 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 product is 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

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

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, polyacrylate-60, potassium sorbate, sodium benzoate, sodium chlyhroxyalyl phosphate, sodium polyacrylate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tropolone, water, xanthan gum

Questions or comments?
1.800.636.7546
Monday–Friday 9a.m.–4p.m. Pacific Time

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OBAGI MEDICAL

NORMAL DRY

Skin Transformation Trial Kit

NU-DERM® SYSTEM

OBAGI MEDICAL

NDC# 62032-528-07

OBAGI MEDICAL - NU-DERM SYSTEM - NORMAL TO DRY - SKIN TRANSFORMATION TRIAL KIT

octinoxate, zinc oxide kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62032-528

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-528-07	1 in 1 CARTON; Type 0: Not a Combination Product	11/16/2015	

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

Part 1 of 6

OBAGI NU-DERM SUN SHIELD MATTE BROAD SPECTRUM SPF 50

sunscreen 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**
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	

HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)	
SQUALANE (UNII: GW89575KF9)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TROPOLONE (UNII: 7L6DL16P1T)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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		

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

WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

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 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**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
LACTIC ACID (UNII: 33X04XA5AT)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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 4 of 6

OBAGI NU-DERM GENTLE CLEANSER

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

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**SODIUM LAUROYL OAT AMINO ACIDS** (UNII: FSW2K9B9N5)	
INGR	**ALOE VERA LEAF** (UNII: ZY81Z83H0X)	
INGR	**SODIUM LAURETH-3 SULFATE** (UNII: BPV390UAP0)	
INGR	**GLYCERETH-7** (UNII: 3D2Y91QZ2H)	
INGR	**APRICOT KERNEL OIL** (UNII: 54JB35T06A)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)** (UNII: 59TL3WG5CO)	
INGR	**OLEYL LACTATE** (UNII: B3AWW0N3GM)	
INGR	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**SAGE** (UNII: 065C5D077J)	
INGR	**BORAGE** (UNII: PB618V0K2W)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 5 of 6

OBAGI NU-DERM TONER

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

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**HAMAMELIS VIRGINIANA TOP WATER** (UNII: NT00Y05A2V)	
INGR	**ALOE VERA LEAF** (UNII: ZY81Z83H0X)	
INGR	**POTASSIUM ALUM** (UNII: 1L24V9R23S)	

INGR	**SODIUM PYRROLIDONE CARBOXYLATE** (UNII: 469OTG57A2)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**DMDM HYDANTOIN** (UNII: BYR0546TOW)	
INGR	**POLYSORBATE 80** (UNII: 6OZP39ZG8H)	
INGR	**ALLANTOIN** (UNII: 344S277G0Z)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**SAGE** (UNII: 065C5D077J)	
INGR	**BORAGE** (UNII: PB618V0K2W)	
INGR	**CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD)	
INGR	**IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB)	
INGR	**FD&C BLUE NO. 1** (UNII: H3R47K3TBD)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 6 of 6

OBAGI NU-DERM EXFODERM

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

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**FYTIC ACID** (UNII: 7IGF0S7R8I)	
INGR	**CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S)	
INGR	**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)	
INGR	**PEG-100 STEARATE** (UNII: YD01N1999R)	
INGR	**MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC)	
INGR	**CANOLA OIL** (UNII: 331KBJ17RK)	
INGR	**ISOHEXADECANE** (UNII: 918X1OUF1E)	
INGR	**POTASSIUM CETYL PHOSPHATE** (UNII: 03KCY6P7UT)	
INGR	**CETYL ALCOHOL** (UNII: 936JST6JCN)	
INGR	**DIMETHICONE** (UNII: 92RU3N3Y1O)	
INGR	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	
INGR	**XANTHAN GUM** (UNII: TTV12P4NEE)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**GLYCERETH-7** (UNII: 3D2Y91QZ2H)	
INGR	**POLYSORBATE 60** (UNII: CAL22UVI4M)	

INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**PEG-150 STEARATE** (UNII: 7BSG7DF10Q)	
INGR	**STEARETH-20** (UNII: L0Q8IK9E08)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		11/16/2015	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-528)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-528), REPACK(62032-528)

Revised: 11/2019 Obagi Cosmeceuticals LLC