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, bisdiglyceryl 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



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



NORMAL DRY
Skin Transformation Trial Kit

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

A result colour ceasured must previous gentle yet effective cleaning by estimate to any sent, not sent that is becautifully clean and freach, the Null-Orm Gorded Colorose instantly dissolves excess oil, makes, 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 regiment.

Directions: Use twice daily, marning and evening. Massage a small amount of cleanser and water onto skin Rinse with lukewern water and gently pat dry.

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

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Toner 2 fl nz [59 ml] AM+PM

An essential step in your daily skin care routine, this alcohol-free, nondrying taner helps adjust your skin's pH.
Use after cleanning to remove impurities and dead skin cells and to prepare the skin for hydration or appropriate

Directions: Use daily, in the morning and evening after cleansing. Shake before use. Saturate a cotton pad and purely wire over eather hore. Do not since

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

gredients: water (aque), harnamelis virginiana (witch hazel) water, alice barbadensis loof julco, potassium um, sedum PCA, pumberol, MEDM hydertein, polyesthate 10, ollartein, plysein, salais officinialis (sage) lea tract, borago officinialis extract, calendula efficinalis flower extract, seponins, isdopropyrej burlykarbamaza, sprance (partury), bas 1 (Cl 42000)

Clear (Skin Bleaching and Corrector Cream) NDC 62032-101-36

Net wt. Z 02, 157 g) Hydroquinone USP, 4% RX only AM+PM Dark spsts noy operor on the unitical elysis skill, but they actually start deep within the skill's layers. This parties pit officiale formula absorbs into the layers of your skill to deliver prescription-straight hydroquinose, beliefs to convert the acreascence of the end of your owns for a hashifter, more new proceedings.

ndications and usage: The gradual bleaching of hyperpigmented skin conditions such as chlosoms, melasms,

Decage and administration: Use Cally, in the results and energia, Squeeze a areal ensural paper similarly 1-2 per-los amounted sets a beautiful position of the entire face, extending to this labilities, on the cera and extended in distaltating motion, or as distalted by para physician. If no improvement is seen after treat just and individually out of this product should be discontinued. See degrees who all be in their by using a season reading and protection of chings to come blacked all who has using and after the common part of the protection of chings to come blacked all who has using and after the common part of the common parameters.

Wornings: Avoid centact with eyes, nose, mouth, and lips. In case of accidental contact, patient should rinso thoroughly with water and centact a physician. Suscerom use is an essential aspect of hydroganizate theraps because even minimal until deposit or usuation melanovitic activity.

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Each aram of Obaci No. Denn Clear contains

Active ingredient: Hydroquinone USP, 4% (40 mg

Timathive ingredients: write, only alcohol, glycerin, sodium laury) saffate, steery alcohol, factic acid, tocaphery) acetate, oscerbic acid, sodium metables little, disodium EDTA, methylparaben, EHT, propylparaben, saperirs, buty paraben

ee 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 larger that exhibites the too law of skin, removing dul, all skin cells while revealing an

A lightweight lation that exhibition the top layer of six is, removing dust, all dain cells white revealing new sain cells for a brighter complexion. Specifically developed for normal to dry skin, this gentle, skin-entrancing fermula certains a plant acid (phytic acid) to help transform the appearance of damaged skin and reveal year skin's radiance.

Birections: Use daily, in the morning, Squeeze a small amount japproximately 1-2 pec-size draps) onto your hunds. Using your fingertips, apply evenly to the entire face. Massage until completely absorbed.

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

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Blender® (Skin Lightener and Blending Cream) NDC 62032-100-10 Net wt. 1 oz. (28 g) Hydroquinone USP, 4% Rx only PM

Lunkque formalo containing prescription-utength hydroquisone for the grodouf lightening of sun opers, ag pets, and after types of hypergigmentation (discaleration). Specially formalated to optimize the delisary or cocket ingredents in the Niu-Derm System, this skin lightener helps reduce signs of aging by consocing

Indications and usage: The gradual bleaching of hyperpigmentad skin conditions such as chlossmo, melasmo

Desage and administration: Use daily, in the eneming. Squeeze a small amount approximately 1-2 per-size drops after good manual approximately 1-2 per-size drops after good manual population and provided in the propose and approximately for a size of a personal population and approximately for a propose and approximately for a propose and another three (5) ments of the attention appeared productive defining a cover bleathed six in when using another productive defining to cover bleathed six in when using another productive defining to cover bleathed six in when using another productive control in a size for a possible daily and approximately approximate

Warnings: Avoid contact with eyes, nose, mouth, and lips. In case of assidental contact, patient should rinse thoroughly with water and contact a physician. Sunscreen use is an exeential aspect of

entains sodium metabioulite, a suffite first may cause aftergic-type resections including anaphylactic imptorus and life-theostesing or less severe authenatic episodes in certain susceptible people. The cerall prevalence of suffite sensitivity is the general population is unknown and probably ices. Suffite analizing is seen mante brogonathy in authenatic than in nananthematic people.

ach gram of Obagi Nu-Dann Blender contains:

nactive ingression representation of the Workship and the PPG-2 reprintyl efter propionate, and um learly suffiliancifive ingredients users, algorini, carly labeled, PPG-2 reprintyl efter propionate, and um learly suffi-TEA-solicytate, lactic acid, ghenyl trineshipose, tocopheral ocetate, occlum metablishifive, ascorbic acid, methylyarabon, disolatur (EDA, propiparabon, spoprins, MHT).

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).

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www.obagi.com 9458302

Sun Shield Broad Spectrum SPF 50 Matte Net wt. 1 oz. [28 g]

This suncern cambines UVB absorption and UVA protection in an elegant matte finish that is non-cornedogenic, hypoallergenic, non-scnegenic, and dermatologist tested. Sheer, PABA for

Active ingredients Purpose

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Uses

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Directions

Drug Facts

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swim
- children under 6 months: Ask a doct
- Sun Protection Measures. Spending time in the sun increases your risk of sk cancer and early skin aging To decrease this risk, regularly use a sunscreen was Brood Spectrum SPF value of 15 or higher and other sun protection measure including.
- limit time in the sun, especially from 10 a.m.-2 p.m.

wear long-sleeved shirts, pants, hats,

■ store at controlled room temperature: 15°C-25°C (59°F-77

nactive ingredients

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Questions or comments?

1.800.636.7546 Monday-Friday Sa.m.-4p.m. Pacific Time







Skin Transformation Trial Kit

VAU JAMAON

NN-DERM®SYSTEM



NOC# 95035-258-03

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

octinoxate, zinc oxide kit

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Pro	duct	Intori	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:62032-528

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

Quantity of Parts

Quan	Quantity of 1 at 15		
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-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
GLYCERIN (UNII: PDC6A3C0OX)	

HYDRO GENATED PALM GLYCERIDES (UNII: YCZ8 EM144Q)	
HYDRO XYETHYL ACRYLATE/SODIUM ACRYLO YLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PENTYLENE GLYCOL (UNII: 50 C130 7 PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)	
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)	

l	Pa	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	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
HYDRO Q UINO NE (UNII: XV74C1N1AE) (HYDRO Q UINO NE - 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: 2KR8914H1Y)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A218 C7HI9T)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
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		0 1/0 1/19 8 8	

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
HYDRO Q UINO NE (UNII: XV74C1N1AE) (HYDRO Q UINO NE - 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: H8 O 40 40 BHD)	
LACTIC ACID (UNII: 33X04XA5AT)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	ackaging			
#	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		0 1/0 1/19 8 8	

Part 4 of 6

OBAGI NU-DERM GENTLE CLEANSER

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

Product Information	
Route of Administration	TOPICAL

Other Ingred	ients	
Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
INGR	GLYCERIN (UNII: PDC6 A3C0 O X)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
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: A1A118 X02B)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	BORAGE (UNII: PB618V0K2W)	
INGR	PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
INGR	FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	

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 INGR WATER (UNII: 059QF0KO0R) HAMAMELIS VIRCINIANA TOR WATER (UNII: NT00V05A2V)

INGR	WATER (UNII: 059QF0KO0R)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
INGR	ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	

Quantity

INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469 OTG57A2)
INGR	PANTHENOL (UNII: WV9CM0O67Z)
INGR	DMDM HYDANTO IN (UNII: BYR0546 TOW)
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)
INGR	ALLANTOIN (UNII: 344S277G0Z)
INGR	GLYCERIN (UNII: PDC6 A3C0 OX)
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: A1A1I8 X02B)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	FYTIC ACID (UNII: 7IGF0 S7R8 I)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4 V 0 N C)	
INGR	CANOLA OIL (UNII: 331KBJ17RK)	
INGR	ISO HEXADECANE (UNII: 918 X10 UF1E)	
INGR	POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	DIMETHICO NE (UNII: 92RU3N3Y1O)	
INGR	SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	PHENO XYETHANO L (UNII: HIE 49 2 Z Z 3 T)	
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	.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
INGR	ETHYLPARABEN (UNII: 14255EXE39)			
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)			
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)			
INGR	PROPYLPARABEN (UNII: Z8 IX2SC1OH)			

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.		0 170 14734	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