

**OBAGI NU-DERM SYSTEM NORMAL-DRY SKIN TRANSFORMATION TRIAL-
hydroquinone, homosalate, octisalate, 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® Nu-Derm® System Normal-Dry Skin Transformation Trial

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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 Olivatate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

Questions or comments?

1.800.636.7546 Monday–Friday 9 a.m.–4 p.m. PST

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

OBAGI®
MEDICAL

OBAGI NU-DERM® 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

OBAGI[®]
MEDICAL

OBAGI NU-DERM[®] 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

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

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

Drug Facts (continued)

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 Oliviate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

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



Questions or comments?

1.800.636.7546 Monday–Friday 9 a.m.–4 p.m. PST

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

FOR ALL PRODUCTS

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.**

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

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Made in USA with US and imported components. 855810222-1

Gentle Cleanser | 2 fl. oz. [59 mL]

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.

Ingredients: Water (Aqua), Cocamidopropyl Betaine, Glycerin, Sodium Lauroyl Oat Amino Acids, Aloe Barbadensis Leaf Juice, Sodium Laureth Sulfate, Glyceth-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]

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.

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)

Exfoderm® (Skin Smoothing Lotion) | Net wt. 1 oz. [28 g]

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.

Ingredients: Water (Aqua), Ethoxydiglycol, Phytic Acid, Glycerin, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Canola Oil, Isohexadecane, Magnesium Aluminum Silicate, Potassium Cetyl Phosphate, Bis-Diglyceryl Polyacryladipate-2, Cetyl Alcohol, Dimethicone, Xanthan Gum, Sodium Hydroxide, Phenoxyethanol, Glyceth-7, Polysorbate 60, Methylparaben, Steareth-20, PEG-150 Distearate, Tocopheryl Acetate, Saponins, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben

Clear (Skin Bleaching and Corrector Cream)

Hydroquinone USP, 4% Rx only NDC 62032-101-36

Net wt. 2 oz. [57 g]

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 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 prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Blender® (Skin Lightener and Blending Cream)

Hydroquinone USP, 4% Rx only NDC 62032-100-10

Net wt. 2 oz. [57 g]

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 (Aqua), 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.

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 Obagi Nu-Derm® Gentle Cleanser is designed to instantly dissolve 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.

Toner | 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 while preparing the skin for hydration or appropriate products.

Clear (Skin Bleaching and Corrector Cream) | AM+PM

Hydroquinone USP, 4% Rx Only, NDC 62032-101-36

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 dark spots for a healthier-looking, more even complexion.

Exfoderm® (Skin Smoothing Lotion) | 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 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.

Blender® (Skin Lightener and Blending Cream) | PM

Hydroquinone USP, 4% Rx Only, NDC 62032-100-10

A unique formula containing prescription-strength hydroquinone for the gradual lightening of sun spots or age spots and other types of hyperpigmentation (discoloration). Specially formulated to optimize the delivery of product ingredients in the Obagi Nu-Derm® System, this skin lightener helps reduce signs of aging by correcting uneven skin tone.

Sun Shield Matte Broad Spectrum SPF 50 | 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.



OBAGI NU-DERM SYSTEM NORMAL-DRY SKIN TRANSFORMATION TRIAL

hydroquinone, homosalate, octisalate, zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-913
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-913-01	1 in 1 CARTON	06/25/2021	06/25/2025

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	0 BOTTLE, PLASTIC	28 g
Part 6	1 TUBE	28 g

Part 1 of 6

NU-DERM TONER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] 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: WW9CM0O67Z)	
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)	

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		01/02/1988	

Part 2 of 6

NU-DERM GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] 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 INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
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: W9CM0O67Z)	
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)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		50 mL (1.7 FL OZ) BOTTLE, PLASTIC, Type 3, Not for		

1	59 mL in 1 BOTTLE, PLASTIC; Type O: Not a Combination Product		
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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

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] cream

Product Information

Item Code (Source)	NDC:62032-101
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	NDC:62032-101-36	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 SKIN SMOOTHING

face and neck (excluding shaving preparations), leave-on [skin care preparations (creams, lotions, powder, and sprays)] lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	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 MONOSTEARATE (UNII: YD01N1999R)	
INGR	DIMETHICONE, UNSPECIFIED (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)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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

Item Code (Source)	NDC:62032-100
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	NDC:62032-100-36	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 6 of 6

SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

Item Code (Source)	NDC:62032-140
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, UNSPECIFIED (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	NDC:62032-140-05	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 DRUG	M020	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 Cosmeceuticals LLC (790553353)

Registrant - Swiss American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-913)

Establishment

Name	Address	ID/FEI	Business Operations
G. S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-913)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		118417470	PACK(62032-913) , LABEL(62032-913)

Revised: 10/2025

Obagi Cosmeceuticals LLC