

**OBAGI NU-DERM FX SYSTEM NORMAL - OILY SKIN TRANSFORMATION
COMPLEXION BRIGHTENING SYSTEM- homosalate, octisalate, and zinc oxide
Obagi Cosmeceuticals LLC**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**Obagi® Nu-Derm FX™ System Normal - Oily
Skin Transformation Kit Complexion Brightening System**

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 Olivatate, Silica, Polyglyceryl-6 Polyricinoleate, 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

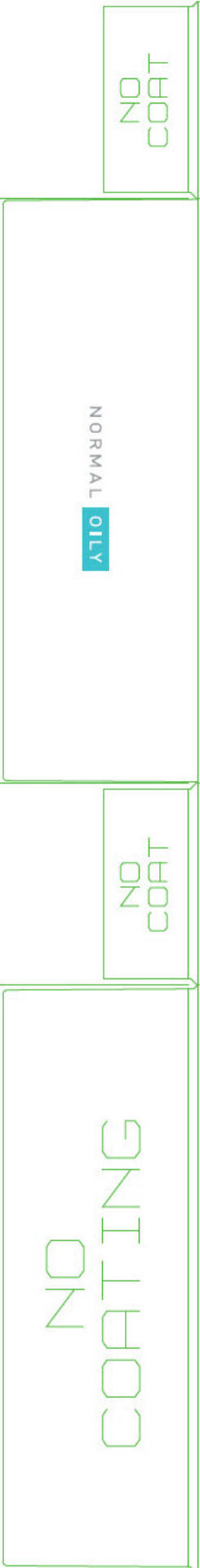
PRINCIPAL DISPLAY PANEL - Kit Carton

OBAGI®
MEDICAL

OBAGI NU-DERM FX™
SYSTEM

NORMAL OILY

Skin Transformation Kit
Complexion Brightening System



OBAGI NU-DERM FX SYSTEM NORMAL - OILY SKIN TRANSFORMATION COMPLEXION BRIGHTENING SYSTEM

homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-538
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-538-91	1 in 1 CARTON	12/02/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	198 mL
Part 2	1 BOTTLE, PLASTIC	198 mL
Part 3	1 BOTTLE, PLASTIC	57 g
Part 4	1 BOTTLE, PLASTIC	57 g
Part 5	1 BOTTLE, PLASTIC	48 g
Part 6	1 BOTTLE, PLASTIC	57 g
Part 7	1 TUBE	85 g

Part 1 of 7

NU-DERM FOAMING

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

Product Information

Route of Administration	TOPICAL
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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	ALFALFA (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

color	RED	C48326
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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 7

NU-DERM TONER

face and neck (excluding shaving preparations) liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
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)	

Product Characteristics

color	BLUE	C48333
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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 7

NU-DERM CLEAR FX SKIN BRIGHTENING

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	ARBUTIN (UNII: C5INA23HXF)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

color	WHITE	C48325
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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
Cosmetic		01/01/1988	

Part 4 of 7

NU-DERM EXFODERM FORTE EXFOLIATION ENHANCER

lotions, oils, powders, and creams 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	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)
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Product Characteristics

color	WHITE	C48325
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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
Cosmetic		01/01/1988	

Part 5 of 7

NU-DERM HYDRATE FACIAL MOISTURIZER

moisturizing 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	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	LAURETH-12 (UNII: OAH19558U1)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
INGR	SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Product Characteristics

color	WHITE	C48325
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 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		11/07/2012	

Part 6 of 7

NU-DERM BLEND FX SKIN BRIGHTENER AND BLENDING

cleansing (cold creams, cleansing lotions, liquids, and pads) 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: PDC6A3C00X)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	

INGR	ARBUTIN (UNII: C5INA23HXF)	
INGR	PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	METHYLPARABEN (UNII: A218C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

color	WHITE	C48325
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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
Cosmetic		01/01/1988	

Part 7 of 7

NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

Route of Administration	TOPICAL
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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 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
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Unapproved drug other		12/02/2019	
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Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-538)

Establishment

Name	Address	ID/FEI	Business Operations
G. S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-538)

Revised: 1/2023

Obagi Cosmeceuticals LLC