

**OBAGI NU-DERM FX SYSTEM NORMAL - DRY 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.*

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

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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 DRY

Skin Transformation Kit  
Complexion Brightening System



NO  
COATING

NO  
COAT

NORMAL  
DRY

NO  
COAT

# OBAGI NU-DERM FX SYSTEM NORMAL - DRY SKIN TRANSFORMATION COMPLEXION BRIGHTENING SYSTEM

homosalate, octisalate, and zinc oxide kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62032-539
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-539-07	1 in 1 CARTON	12/02/2019	

## Quantity of Parts

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

## Part 1 of 7

### NU-DERM GENTLE CLEANSER

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

## Product Information

<b>Route of Administration</b>	TOPICAL
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## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
INGR	<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	

INGR	<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
INGR	<b>SODIUM LAUROYL OAT AMINO ACIDS</b> (UNII: FSW2K9B9N5)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
INGR	<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>GLYCERETH-7</b> (UNII: 3D2Y91QZ2H)	
INGR	<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
INGR	<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A1I8X02B)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
INGR	<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)	
INGR	<b>OLEYL LACTATE</b> (UNII: B3AVW0N3GM)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
COLR	<b>Yellow</b> ()	

### 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

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	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V)	
INGR	<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	

INGR	<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
INGR	<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
INGR	<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)	
INGR	<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
INGR	<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
INGR	<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
COLR	<b>BLUE</b> ()	

### 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) [skin care preparations (creams, lotions, powder, and sprays)] liquid

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>ARBUTIN</b> (UNII: C5INA23HXF)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
INGR	<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	

INGR	<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
INGR	<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
COLR	<b>WHITE</b> ()	

### 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 SKIN SMOOTHING

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

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
INGR	<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
INGR	<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
INGR	<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
INGR	<b>CANOLA OIL</b> (UNII: 331KBJ17RK)	
INGR	<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
INGR	<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	

INGR	<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	
INGR	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
INGR	<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
INGR	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
INGR	<b>PEG-150 STEARATE</b> (UNII: 7BSG7DF10Q)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
INGR	<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
INGR	<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
INGR	<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>GLYCERETH-7</b> (UNII: 3D2Y91QZ2H)	
INGR	<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A1I8X02B)	
INGR	<b>BIS-DIGLYCERYL POLYACYLADIPATE-2</b> (UNII: 6L246LAM9T)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
COLR	<b>BLUE</b> ()	

### 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 [skin care preparations (creams, lotions, powder, and sprays)] lotion

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0K00R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>TARA SPINOSA RESIN</b> (UNII: WL3883U2PO)	
INGR	<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
INGR	<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
INGR	<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	
INGR	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
INGR	<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
INGR	<b>LAURETH-12</b> (UNII: OAH19558U1)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
INGR	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
INGR	<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
INGR	<b>SOY STEROL</b> (UNII: PL360EPO9J)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
INGR	<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
INGR	<b>TETRAHYDRODIFERULOYLMETHANE</b> (UNII: 00U0645U03)	
INGR	<b>PANTHENOL</b> (UNII: VW9CM0O67Z)	
INGR	<b>MANGIFERA INDICA SEED BUTTER</b> (UNII: 4OXD9M35X2)	
INGR	<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
INGR	<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
INGR	<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
COLR	<b>WHITE</b> ()	

### 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) [skin care preparations (creams, lotions, powder, and sprays)] lotion

## Product Information

Route of Administration TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>ARBUTIN</b> (UNII: C5INA23HXF)	
INGR	<b>PPG-2 MYRISTYL ETHER PROPIONATE</b> (UNII: 88R97D8U8A)	
INGR	<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
INGR	<b>TROLAMINE SALICYLATE</b> (UNII: H8O4040BHD)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
INGR	<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
INGR	<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
INGR	<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
COLR	<b>WHITE</b> ()	

## 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

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>C15-19 ALKANE</b> (UNII: CI87N1IM01)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>POLYGLYCERYL-2 ISOSTEARATE</b> (UNII: 7B8OE71MQC)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## 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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	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)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-539)

### Establishment

Name	Address	ID/FEI	Business Operations
G. S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-539)

Revised: 4/2025

Obagi Cosmeceuticals LLC