

# **OBAGI SKINTRINSIQ BRIGHTENING PROTOCOL- homosalate, octisalate, and zinc oxide**

**Obagi Cosmeceuticals LLC**

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**Obagi<sup>®</sup> Skintrinsiq Brightening Protocol Kit**

**Obagi<sup>®</sup> Sun Shield Matte Broad Spectrum SPF 50 Sunscreen**

## ***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></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°-25°C (59°-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, Distearidimonium 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**

SKINTRINSIQ™

BRIGHTENING  
PROTOCOL KIT

#### **INCLUDES:**

- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- Obagi Nu-Derm® Clear Fx, 2 FL. OZ.
- Obagi Hydrate® Facial Moisturizer, 1.7 OZ.
- Obagi Sun Shield™ Matte Broad Spectrum SPF 50 Sunscreen, 3 OZ.

OBAGI®

OBAGI

SKINTRINSIQ™

2.742



# BRIGHTENING PROTOCOL KIT

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- Obagi Hydrate® Facial Moisturizer, 1.7 OZ.
- Obagi Sun Shield™ Matte Broad Spectrum SPF 50 Sunscreen, 3 OZ.

SKINTRINSIQ™

OBAGI



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# BRIGHTENING

## PROTOCOL KIT

30 Treatments

This box contains 60 treatment tips and one of each of the products listed on the front of this carton.

For more information on the products in this kit and usage instructions, please see product packaging.

Manufactured for Obagi Cosmetics, Inc., Long Beach, CA 90806  
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### PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

OBAGI®  
MEDICAL

Sun Shield

MATTE

Broad  
Spectrum  
SPF 50

Sunscreen  
Lotion

Non-Comedogenic  
Dermatologist Tested

Net wt. 3 oz (85 g)

**Sun Shield Matte Broad Spectrum SPF 50**  
 This sunscreen provides broad spectrum protection against UVB and UVA radiation in an elegant, matte finish that is non-comedogenic, hypoallergenic and dermatologist tested. Sheer and fragrance free for all skin types.

**Drug Facts**

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**Directions**

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- reapply at least every 2 hours
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  - 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**

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**Inactive ingredients**

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivrate, Silica, Polyglyceryl-6 Polyriboisolate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Diethylammonium Hydroxide, 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



**Sun Shield**

**MATTE** Broad Spectrum SPF 50  
  
 Sunscreen Lotion

Non-Comedogenic  
 Dermatologist Tested

Net wt. 3 oz (85 g)

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806  
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# OBAGI SKINTRINSIQ BRIGHTENING PROTOCOL

homosalate, octisalate, and zinc oxide kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62032-905
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-905-05	1 in 1 BOX	08/01/2021	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 BOTTLE, PLASTIC	60 mL
<b>Part 2</b>	1 BOTTLE, PLASTIC	59 mL
<b>Part 3</b>	1 BOTTLE, PLASTIC	57 g
<b>Part 4</b>	1 BOTTLE, PUMP	48 g
<b>Part 5</b>	1 TUBE	85 g

## Part 1 of 5

### OBAGI NU-DERM GENTLE CLEANSER

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

## Product Information

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

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
INGR	<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A18X02B)	
INGR	<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	

INGR	<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
INGR	<b>GLYCERETH-7</b> (UNII: 3D2Y91QZ2H)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>OLEYL LACTATE</b> (UNII: B3AWW0N3GM)	
INGR	<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
INGR	<b>SODIUM LAUROYL OAT AMINO ACIDS</b> (UNII: FSW2K9B9N5)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 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		08/01/2021	

## Part 2 of 5

### OBAGI NU-DERM TONER

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>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
INGR	<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
INGR	<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
INGR	<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V)	
INGR	<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
INGR	<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
INGR	<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
INGR	<b>WATER</b> (UNII: 059QF0K00R)	

### 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		08/01/2021	

### Part 3 of 5

#### OBAGI NU-DERM CLEAR FX

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

### Product Information

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

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>ARBUTIN</b> (UNII: C5INA23HXF)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
INGR	<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

INGR	<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
INGR	<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
INGR	<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	

### 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		08/01/2021	

### Part 4 of 5

## OBAGI 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>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
INGR	<b>TARA SPINOSA RESIN</b> (UNII: WL3883U2PO)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
INGR	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
INGR	<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
INGR	<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
INGR	<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
INGR	<b>LAURETH-12</b> (UNII: OAH19558U1)	
INGR	<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	

INGR	<b>MANGIFERA INDICA SEED BUTTER</b> (UNII: 4OXD9M35X2)	
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
INGR	<b>PANTHENOL</b> (UNII: W9CM0067Z)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	
INGR	<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
INGR	<b>SOY STEROL</b> (UNII: PL360EPO9J)	
INGR	<b>SOYBEAN</b> (UNII: L7HT8F1ZOD)	
INGR	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
INGR	<b>TETRAHYDRODIFERULOYLMETHANE</b> (UNII: 00U0645U03)	
INGR	<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		48 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		08/01/2021	

### Part 5 of 5

## SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

### Product Information

<b>Item Code (Source)</b>	NDC:62032-140
<b>Route of Administration</b>	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>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>C15-19 ALKANE</b> (UNII: CI87N1IM01)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>POLYGLYCERYL-2 ISOSTEARATE</b> (UNII: 7B8OE71MQC)	
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-140-09	1 in 1 CARTON		
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 Drug	M020	08/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/01/2021	

## Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA, INC.		017014734	manufacture(62032-905)

## Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(62032-905)

## Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(62032-905)

## Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	pack(62032-905)

Revised: 3/2025

Obagi Cosmeceuticals LLC