

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

Obagi Cosmeceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Obagi® Skintrinsiq Brightening Protocol Kit

Obagi® Sun Shield Matte Broad Spectrum SPF 50 Sunscreen

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°-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®



SKINTRINSIQ™

2.742



BRIGHTENING PROTOCOL KIT

INCLUDES:

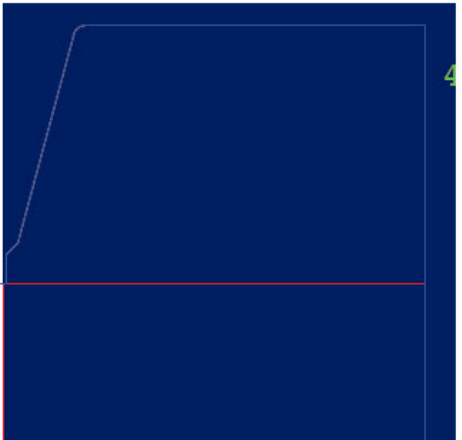
- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- Obagi Nu-Derm® Clear Fx, 2 FL. OZ.
- Obagi Hydrate® Facial Moisturizer, 1.7 OZ.
- Obagi Sun Shield™ Matte Broad Spectrum SPF 50 Sunscreen, 3 OZ.



SKINTRINSIQ™



4





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.

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Inactive ingredients

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivrate, Silica, Polyglyceryl-8 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
Part 1	1 BOTTLE, PLASTIC	60 mL
Part 2	1 BOTTLE, PLASTIC	59 mL
Part 3	1 BOTTLE, PLASTIC	57 g
Part 4	1 BOTTLE, PUMP	48 g
Part 5	1 TUBE	85 g

Part 1 of 5

OBAGI NU-DERM GENTLE CLEANSER

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	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	OLEYL LACTATE (UNII: B3AWW0N3GM)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PROPYLPARABEN (UNII: Z8IX25C1OH)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	WATER (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) liquid

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	

INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	WATER (UNII: 059QF0KO0R)	

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) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ARBUTIN (UNII: C5INA23HXF)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	WATER (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 lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	LAURETH-12 (UNII: OAH19558U1)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	SOYBEAN (UNII: L7HT8F1ZOD)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	WATER (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

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
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

C15-19 ALKANE (UNII: C187N1M01)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SORBITAN OLIVATE (UNII: MDL271E3GR)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)
YELLOW WAX (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 final	M020	08/01/2021	

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

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment			
Name	Address	ID/FEI	Business Operations

G.S.COSMECEUTICAL USA, INC.		017014734	manufacture(62032-905)
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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: 3/2023

Obagi Cosmeceuticals LLC