

OBAGI SKINTRINSIQ FIRMING PROTOCOL- titanium dioxide 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 Firming Protocol Kit

Obagi® Sun Shield Mineral Broad Spectrum SPF 50 Sunscreen

Drug Facts

Active ingredients	Purpose
Titanium dioxide 6.2%	Sunscreen
Zinc oxide 15.6%	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

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

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
- children under 6 months: Ask a doctor
- **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

Inactive ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Dicaprylyl Carbonate, Pentylene Glycol, Steareth-2, Glycerin, Silica, Polyhydroxystearic Acid, Steareth-21, Cetearyl Alcohol, Propanediol, Alumina, Stearic Acid, Sodium Stearoyl Glutamate, Caprylyl Glycol, Triethoxycaprylylsilane, Cetearyl Glucoside, Xanthan Gum, Dipotassium Glycyrrhizate, Trisodium Ethylenediamine Disuccinate, Caprylhydroxamic Acid, Tropaeolum Majus Flower/Leaf/Stem Extract

Other information

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

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™

FIRMING
PROTOCOL KIT

INCLUDES:

- 60 Tips
- Obagi Nu-Derm® gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- ELASTIderm® Facial Serum, 1.7 OZ.
- Obagi Hydrate Luxe®, 1.7 OZ.
- Obagi Sun Shield™ Mineral Broad Spectrum SPF 50 Sunscreen, 3 OZ.

OBAGI®



SKINTRINSIQ™

2.742



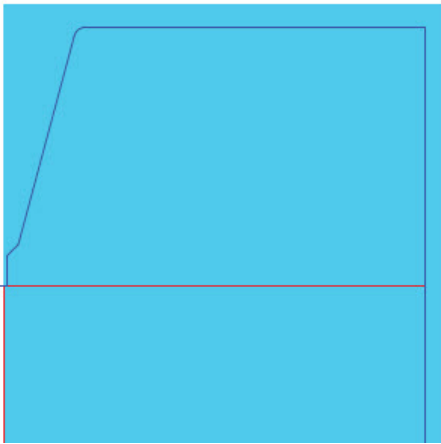
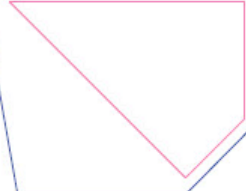
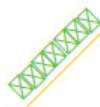
FIRMING PROTOCOL KIT

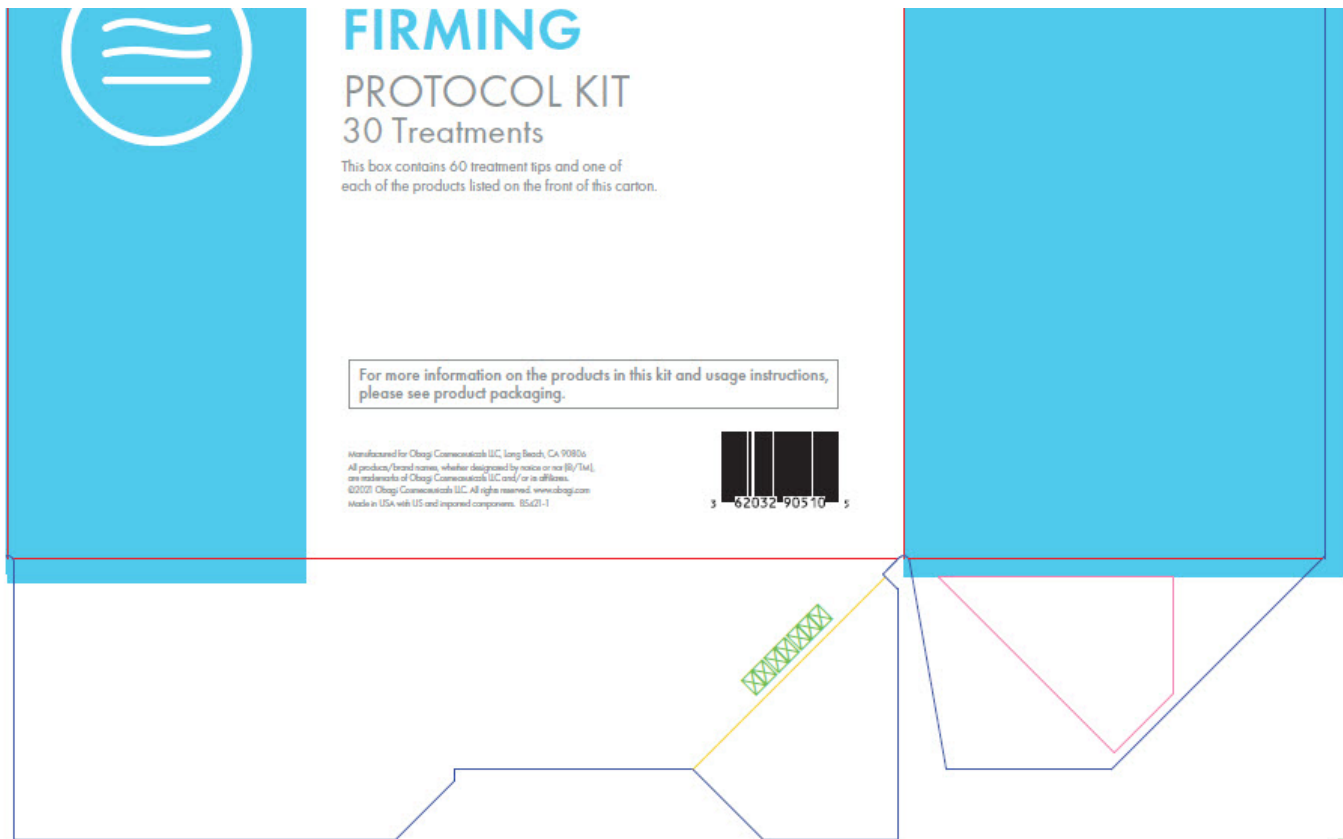
INCLUDES:

- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- ELASTiderm® Facial Serum, 1.7 OZ.
- Obagi Hydrate Luxe® 1.7 OZ.
- Obagi Sun Shield™ Mineral Broad Spectrum SPF 50 Sunscreen, 3 OZ.



SKINTRINSIQ™





PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

**OBAGI™
MEDICAL**

Sun Shield

MINERAL

**Broad
Spectrum
SPF 50**

**Sunscreen
Lotion**

**PA++++
Non-comedogenic
Dermatologist Tested**

Net wt. 3 oz. (85 g)

Drug Facts (continued)

Inactive ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Dicaprylyl Carbonate, Pentylene Glycol, Steareth-2, Glycerin, Silica, Polyhydroxystearic Acid, Steareth-21, Cetearyl Alcohol, Propanediol, Alumina, Stearic Acid, Sodium Stearoyl Glutamate, Caprylyl Glycol, Triethoxycaprylylsilane, Cetearyl Glucoside, Xanthan Gum, Dipotassium Glycyrrhizate, Trisodium Ethylenediamine Disuccinate, Caprylhydroxamic Acid, Tropaeolum Majus Flower/Leaf/Stem Extract

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Long Beach, CA 90806
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9457602



Sun Shield
MINERAL Broad Spectrum SPF 50
Sunscreen Lotion



PA++++
Non-comedogenic
Dermatologist Tested

Net wt. 3 oz. (85 g)



Sun Shield Mineral Broad Spectrum SPF 50

An elegant daily sunscreen that protects from UVA and UVB rays with a 100% mineral blend of zinc oxide and titanium dioxide, and provides a lightweight satin finish. This high protection physical sunscreen is also formulated with Nasturtium flower extract to help defend against blue and visible light.

Formulated for all skin types, including sensitive skin.

Drug Facts

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 - wear long-sleeved shirts, pants, hats, and sunglasses

OBAGI SKINTRINSIQ FIRMING PROTOCOL

titanium dioxide and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-910
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-910-10	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, PUMP	30 mL
Part 4	1 JAR	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: Z8IX2SC1OH)	
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: PDC6A3C00X)	
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: 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 ELASTIDERM FACE SERUM

face and neck (excluding shaving preparations) gel

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
INGR	AMODIMETHICONE (1300 CST) (UNII: 3V7U636DWN)	
INGR	BASIC CUPRIC CARBONATE (UNII: GIK928GH0Y)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	

INGR	ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
INGR	MALONIC ACID (UNII: 9KX7ZMG0MK)	
INGR	METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	ZINC CARBONATE (UNII: EQR32Y7H0M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		30 mL 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 4 of 5

OBAGI HYDRATE LUXE

moisturizing cream

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	CAPROOYL TETRAPEPTIDE-3 (UNII: LZ10HJ3K2R)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	DEXTRAN 40 (UNII: K3R6ZDH4DU)	
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: 4OXD9M35X2)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PREZATIDE (UNII: 39TG2H631E)	
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		48 g in 1 JAR; 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 MINERAL BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information

Item Code (Source)	NDC:62032-811
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.2 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPANEDIOL (UNII: 5965N8W85T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
TROPAEOLUM MAJUS FLOWERING TOP (UNII: RGT30824HY)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-811-09	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(62032-910)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(62032-910)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(62032-910)

Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	pack(62032-910)

Revised: 3/2023

Obagi Cosmeceuticals LLC