

OBAGI MEDICAL WAY TO GLOW KIT- 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 Medical Way to Glow Kit

Drug Facts

Active ingredients

Homosalate 10%

Octisalate 5%

Zinc Oxide 16.5%

Purpose

Sunscreen

Sunscreen

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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

Inactive Ingredients

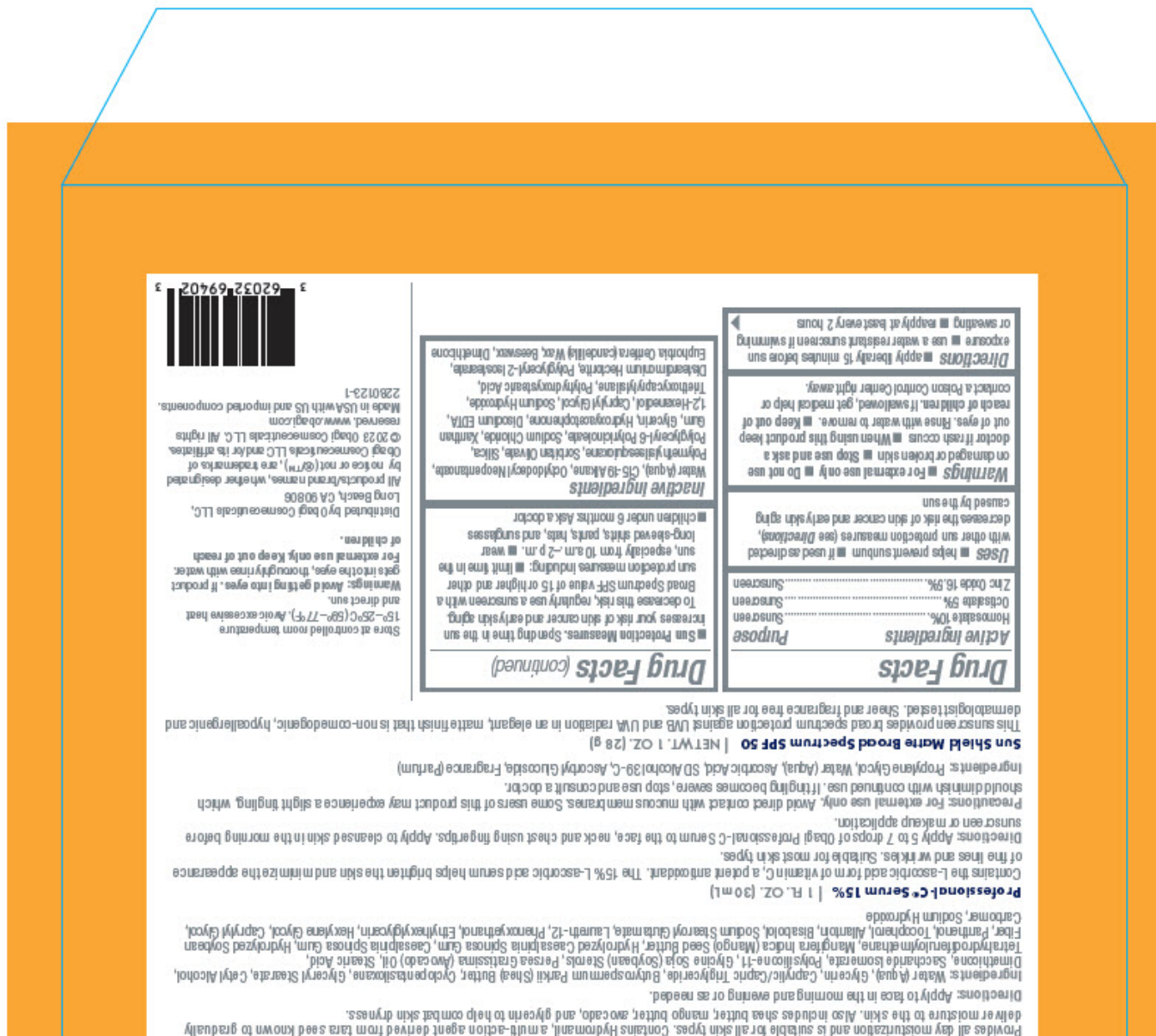
Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivatate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

Way to
Glow
Defend, Hydrate & Protect

OBAGI®
MEDICAL



Way to *Glow*

Defend, Hydrate & Protect



OBAGI MEDICAL WAY TO GLOW KIT

homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-690
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-690-02	1 in 1 CARTON	03/20/2023	
1		1 in 1 BAG; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	28 g
Part 2	1 BOTTLE, DROPPER	30 mL
Part 3	1 BOTTLE, PUMP	48 g

Part 1 of 3

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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
C15-19 ALKANE (UNII: CI87N1IM01)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CANDELILLA WAX (UNII: VL0328HX19)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-140-05	28 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	03/20/2023	

Part 2 of 3

OBAGI MEDICAL PROFESSIONAL-C SERUM 15

face and neck (excluding shaving preparations) liquid

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	EVERNIA PRUNASTRI (UNII: O3034Q5AHK)	
INGR	GRAPEFRUIT PEEL (UNII: 3582N05Q44)	
INGR	ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
INGR	PSEUDEVERNIA FURFURACEA (UNII: 49ZMN09Q0K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/20/2023	

Part 3 of 3

OBAGI MEDICAL OBAGI HYDRATE FACIAL MOISTURIZER

moisturizing lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	PANTHENOL (UNII: W99CM0067Z)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	

INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	LAURETH-12 (UNII: OAH19558U1)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	SOYBEAN (UNII: L7HT8F1ZOD)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
INGR	TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	

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		03/20/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	03/20/2023	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA, INC.		017014734	manufacture(62032-690)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(62032-690)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(62032-690)

Establishment

Name	Address	ID/FEI	Business Operations
Identipak, Inc.		942862350	pack(62032-690)

Revised: 3/2023

Obagi Cosmeceuticals LLC