

**OBAGI MEDICAL BACK TO BASICS (INCLUDING OBAGI MEDICAL PROFESSIONAL-C SERUM 15)- 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 Back to Basics (Including Obagi Medical Professional-C Serum 15%)

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°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, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

Questions or comments?

1.800.636.7546 Monday–Friday 9 a.m.–4 p.m. PST

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

BACK to BASICS

OBAGI®
MEDICAL



OBAGI MEDICAL BACK TO BASICS (INCLUDING OBAGI MEDICAL PROFESSIONAL-C SERUM 15)

homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-694
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-694-02	1 in 1 CARTON	04/01/2022	
1		1 in 1 BAG		

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, DROPPER	30 mL
Part 4	1 TUBE	30 mL
Part 5	1 TUBE	28 g

Part 1 of 5

OBAGI NU-DERM FOAMING

cleansing (cold creams, cleansing lotions, liquids, and pads) gel

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
INGR	ACETYL HEXAMETHYL TETRALIN (UNII: 360Q8Z01IP)	
INGR	MEDICAGO SATIVA WHOLE (UNII: DJO934BRBD)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	BUTYL PARABEN (UNII: 3QPI1U3FV8)	
INGR	BUTYL PHENYL METHYL PROPIONAL (UNII: T7540GJV69)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	DIHYDROMYRCENOL (UNII: 46L1B02ND9)	
INGR	DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
INGR	ETHYL PARABEN (UNII: 14255EXE39)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	GERANYL ACETATE (UNII: 3W81YG7P9R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	HEXYL SALICYLATE (UNII: 8F78EY72YL)	
INGR	HYDROXYISOHXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
INGR	ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC1OH)	
INGR	QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
INGR	SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

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		04/01/2022	

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	.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
INGR	ACETYL HEXAMETHYL TETRALIN (UNII: 360Q8Z01IP)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	DIHYDROMYRCENOL (UNII: 46L1B02ND9)	
INGR	DIOSCOREA VILLOSA TUBER (UNII: IWX3IWX2G8)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	GERANYL ACETATE (UNII: 3W81YG7P9R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
INGR	HEXYL SALICYLATE (UNII: 8F78EY72YL)	
INGR	HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE (UNII: QUE43B9Z2Q)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

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		04/01/2022	

Part 3 of 5

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	ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
INGR	EVERNIA PRUNASTRI (UNII: O3034Q5AHK)	
INGR	GRAPEFRUIT PEEL (UNII: 3582N05Q44)	
INGR	OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	PSEUDEVERNIA FURFURACEA (UNII: 49ZMN09Q0K)	
INGR	WATER (UNII: 059QF0KO0R)	

Packaging

#	Item	Package Description	Marketing Start	Marketing End
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#	Code	Package Description	Date	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		04/01/2022	

Part 4 of 5

OBAGI MEDICAL RETINOL

face and neck (excluding shaving preparations) cream

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: B9J55EA6QX)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	HYPERICUM PERFORATUM FLOWER (UNII: A6V4CUE7PV)	
INGR	JOJOBA OIL (UNII: 724GKU717M)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	

INGR	MALVA SYLVESTRIS FLOWER (UNII: 12X9J152B5)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	PHENOXYETHANOL (UNII: H1E492ZZ3T)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	RETINOL (UNII: G25H0XKK91)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	SORBITOL (UNII: 506T60A25R)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	UBIDECARENONE (UNII: EJ27X76M46)	
INGR	WATER (UNII: 059QF0KO0R)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		04/01/2022	

Part 5 of 5

OBAGI MEDICAL SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
C15-19 ALKANE (UNII: CI87N1IM01)	
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 ISOSTEARATE (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		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	part352	07/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/01/2022	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-694)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(62032-694)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-694)

Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	PACK(62032-694)

Revised: 4/2022

Obagi Cosmeceuticals LLC