

**OBAGI MEDICAL BACK TO BASICS (INCLUDING OBAGI MEDICAL PROFESSIONAL-C SERUM 20)- homosalate, octisalate, and zinc oxide**  
**Obagi Cosmeceuticals LLC**

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**Obagi® Medical Back to Basics (Including Obagi Medical Professional-C Serum 20%)**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</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°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, Distearidimonium 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

## OBAGI MEDICAL BACK TO BASICS (INCLUDING OBAGI MEDICAL PROFESSIONAL-C SERUM 20)

homosalate, octisalate, and zinc oxide kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62032-693
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-693-01	1 in 1 CARTON	04/01/2022	
1		1 in 1 BAG		

### 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, DROPPER	30 mL
<b>Part 4</b>	1 TUBE	30 mL
<b>Part 5</b>	1 TUBE	28 g

## Part 1 of 5

### OBAGI NU-DERM FOAMING

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] 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: 5OCF3011KX)	
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	HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE (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), leave-on [skin care preparations (creams, lotions, powder, and sprays)] 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: IWY3IWX2G8)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	GERANYL ACETATE (UNII: 3W81YG7P9R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
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	<b>PANTHENOL</b> (UNII: W9CM0067Z)	
INGR	<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
INGR	<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
INGR	<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)	
INGR	<b>QUILLAJA SAPONARIA BARK</b> (UNII: 8N0K3807ZW)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SMILAX ARISTOLOCHIIFOLIA ROOT</b> (UNII: NR100Y25G0)	
INGR	<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
INGR	<b>WATER</b> (UNII: 059QF0K00R)	
INGR	<b>YUCCA SCHIDIGERA ROOT</b> (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 20

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>ALCOHOL</b> (UNII: 3K9958V90M)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
INGR	<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)	
INGR	<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZ W74VN)	
INGR	<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A1I8X02B)	
INGR	<b>EVERNIA PRUNASTRI</b> (UNII: O3034Q5AHK)	
INGR	<b>GRAPEFRUIT PEEL</b> (UNII: 3582N05Q44)	
INGR	<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
INGR	<b>OCTOXYNOL-9</b> (UNII: 7JPC6Y25QS)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>PSEUDEVERNIA FURFURACEA</b> (UNII: 49ZMN09Q0K)	
INGR	<b>SORBITOL</b> (UNII: 506T60A25R)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B)	

## 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		04/01/2022	

## Part 4 of 5

### OBAGI MEDICAL RETINOL

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

## Product Information

**Route of Administration** TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: B9J55EA6QX)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
INGR	<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
INGR	<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
INGR	<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
INGR	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
INGR	<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 92RU3N3Y1O)	

INGR	9E4CO0W6C5)	
INGR	<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
INGR	<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
INGR	<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)	
INGR	<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
INGR	<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
INGR	<b>HYPERICUM PERFORATUM FLOWER</b> (UNII: A6V4CUE7PV)	
INGR	<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
INGR	<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
INGR	<b>MALVA SYLVESTRIS FLOWER</b> (UNII: 12X9JI52BS)	
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
INGR	<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>RETINOL</b> (UNII: G2SH0XKK91)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SAMBUCUS NIGRA FLOWER</b> (UNII: 07V4DX094T)	
INGR	<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
INGR	<b>SORBITOL</b> (UNII: 506T60A25R)	
INGR	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
INGR	<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>UBIDECARENONE</b> (UNII: EJ27X76M46)	
INGR	<b>WATER</b> (UNII: 059QF0KOOR)	

### 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
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16.5 g in 100 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		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
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OTC monograph drug	M020	07/15/2019	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph drug	M020	04/01/2022	

**Labeler** - Obagi Cosmeceuticals LLC (790553353)

### Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-693)

### Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(62032-693)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-693)

### Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	PACK(62032-693)

Revised: 3/2025

Obagi Cosmeceuticals LLC