

**OBAGI 360- avobenzone, octinoxate, octisalate, oxybenzone  
OMP, Inc.**

*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.*

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**OBAGI 360™**

**Exfoliating Cleanser AM+PM**

Works to help clear clogged pores that can cause dull, dry, uneven skin. Gentle microbeads aid exfoliation. Gently yet thoroughly cleans your skin to reveal a soft, smooth, radiant complexion.

**Directions**

Use twice daily, morning and evening. Wet hands and face, then massage cleanser onto skin with a gentle circular motion. Rinse with lukewarm water and gently pat dry.

**Warnings**

Avoid getting into eyes. **For external use only. Keep out of reach of children.**

**Ingredients**

water (aqua), polylactic acid, decyl glucoside, glycerin, sodium cocoyl isethionate, cocamidopropyl betaine, sodium lauroamphoacetate, sodium methyl cocoyl taurate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, phenoxyethanol, caprylyl glycol, sodium PCA, panthenol, sodium hydroxide, chlorphenesin, ethylhexylglycerin, hexylene glycol, disodium EDTA, sodium hyaluronate, papain, carbomer, 1,2-hexanediol, algin

**Retinol 0.5 PM**

Gradually releases retinol, refining the appearance of skin texture and tone for clearer-looking skin.

**Directions**

Once daily in the evening, apply a pearl-size amount to the face and gently smooth until absorbed.

**Warnings**

When using this product, you may experience mild redness, peeling, or skin irritation. These are normal, temporary indications the product is working. If irritation occurs, limit use to every other night, or as tolerated. When skin has adjusted, revert to daily use.

Do not use if you are pregnant, lactating, planning to become pregnant, taking prescription acne medication, have compromised skin such as flaring dermatitis, or are undergoing skin peeling treatments. Daily use of a broad spectrum sunscreen with an SPF of 30 or higher is highly recommended.

Avoid getting into eyes. If contact occurs, rinse thoroughly with water. **For external use only. Keep out of reach of children.**

## **Ingredients**

water (aqua), caprylic/capric triglyceride, glyceryl stearate, cyclopentasiloxane, butylene glycol, stearic acid, butyrospermum parkii (shea) butter, polysorbate 60, stearyl alcohol, glycerin, retinol, polysorbate 20, dimethicone, carthamus tinctorius (safflower) seed oil, calendula officinalis flower extract, camellia oleifera leaf extract, camellia sinensis leaf extract, chamomilla recutita (matricaria) flower extract, tocopheryl acetate, ascorbic acid, sodium hyaluronate, cyclohexasiloxane, sorbitol, BHT, bisabolol, allyl methacrylates crosspolymer, dimethicone/vinyl dimethicone crosspolymer, dipotassium glycyrrhizate, disodium EDTA, triethanolamine, carbomer, glyceryl acrylate/acrylic acid copolymer, caprylyl glycol, ethylhexylglycerin, hexylene, glycol, phenoxyethanol

## **HydraFactor Broad Spectrum SPF 30 AM**

### ***Drug Facts***

#### ***Active ingredients***

Avobenzone 1%

Octinoxate 7.5%

Octisalate 5%

Oxybenzone 5%

#### ***Purpose***

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
- 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***

acrylates/C10-30 alkyl acrylate crosspolymer, butyloctyl salicylate, C12-15 alkyl benzoate, caesalpinia spinosa gum, caprylyl glycol, carbomer, dextrin, disodium EDTA, eperua falcata bark extract, ethylhexylglycerin, glycerin, hexylene glycol, hydrolyzed caesalpinia spinosa gum, phenoxyethanol, pichia/resveratrol ferment extract, polysorbate 20, sodium hyaluronate, sodium hydroxide, sorbitan oleate, tocopheryl acetate, ubiquinone, water

***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

**Principal Display Panel - Kit Carton**

**OBAGI 360™**

**Exfoliating Cleanser**

**HydraFactor SPF 30**

**Retinol 0.5**

**OBAGI®**

**MEDICAL**



Exfoliating Cleanser  
Hydrator SPF 30  
Retinol 0.5

OBAGI 360™



A complete approach to skin care, designed to help proactively address early visible signs of aging, while laying the foundation for a lifetime of radiant, healthy-looking skin.

**Exfoliating Cleanser AM + PM**  
5.1 fl. oz. (150 mL)

Works to help clear clogged pores that can cause dull, dry, uneven skin. Gentle microbeads aid exfoliation. Gently yet thoroughly cleans your skin to reveal a soft, smooth, radiant complexion.

**Directions:** Use twice daily, morning and evening. Wet hands and face, then massage deanser onto skin with a gentle circular motion. Rinse with lukewarm water and gently pat dry.

**Warnings:** Avoid getting into eyes. For external use only. Keep out of reach of children.

**Ingredients:** water (aqua), polylactic acid, decyl glucoside, glycerin, sodium cocoyl isethionate, cocamidopropyl betaine, sodium lauroamphoacetate, sodium methyl cocoyl taurate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, phenoxetanol, caprylyl glycol, sodium PCA, panthenol, sodium hydroxide, chlorphenesin, ethylhexylglycerin, hexylene glycol, disodium EDTA, sodium hyaluronate, papain, carbomer, 1,2-hexanediol, algin

**Retinol 0.5 PM**  
Netwt. 1 oz. (28 g)

Gradually releases retinol, refining the appearance of skin texture and tone for clearer-looking skin.

**Directions:** Once daily in the evening, apply a pearl-size amount to the face and gently smooth until absorbed.

**Warnings:** When using this product, you may experience mild redness, peeling, or skin irritation. These are normal, temporary indications the product is working. If irritation occurs, limit use to every other night, or as

**Drug Facts**

Active ingredients	Purpose
Avobenzone 1%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5%	Sunscreen
Oxybenzone 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 ■ 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**



tolerated. When skin has adjusted, revert to daily use.  
 Do not use if you are pregnant, lactating, planning to become pregnant, taking prescription acne medication, have compromised skin such as flaring dermatitis, or are undergoing skin peeling treatments. Daily use of a broad spectrum sunscreen with an SPF of 30 or higher is highly recommended.  
 Avoid getting into eyes. If contact occurs, rinse thoroughly with water. **For external use only. Keep out of reach of children.**  
**Ingredients:** water (aqua), caprylic/capric triglyceride, glyceryl stearate, cyclopentasiloxane, butylene glycol, stearic acid, butyrospermum parkii (shea) butter, polysorbate 60, stearyl alcohol, glycerin, retinol, polysorbate 20, dimethicone, carthamus tinctorius (safflower) seed oil, calendula officinalis flower extract, camellia oleifera leaf extract, camellia sinensis leaf extract, chamomilla recutita (matricaria) flower extract, tocopheryl acetate, ascorbic acid, sodium hyaluronate, cyclohexasiloxane, sorbitol, BHT, bisabolol, allyl methacrylates crosspolymer, dimethicone/vinyl dimethicone crosspolymer, dipotassium glycyrrhizate, disodium EDTA, triethanolamine, carbomer, glyceryl acrylate/acrylic acid copolymer, caprylyl glycol, ethylhexylglycerin, hexylene glycol, phenoxethanol.

**HydraFactor Broad Spectrum SPF 30 AM**  
**Netwt. 2.5 oz. (75 g)**  
 A moisturizer with soothing ingredients and broad spectrum protection to help prevent skin damage caused by UVA/UVB rays.

**inactive ingredients**  
 acrylates/C10-30 alkyl acrylate crosspolymer, butyloctyl salicylate, C12-15 alkyl benzoate, caesalpinia spinosa gum, caprylyl glycol, carbomer, dextrin, disodium EDTA, eperua falcata bark extract, ethylhexylglycerin, glycerin, hexylene glycol, hydrolyzed caesalpinia spinosa gum, phenoxyethanol, pichia/resveratrol ferment extract, polysorbate 20, sodium hyaluronate, sodium hydroxide, sorbitan oleate, tocopheryl acetate, ubiquinone, water

**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

Store at controlled room temperature: 15°C–25°C (59°F–77°F). Keep out of direct sunlight. Recyclable

**1-800-636-7546**  
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## OBAGI 360

avobenzone, octinoxate, octisalate, oxybenzone kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62032-580
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-580-88	1 in 1 CARTON; Type 0: Not a Combination Product	09/08/2015	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	75 g
Part 2	1 TUBE	28 g
Part 3	1 TUBE	150 mL

## Part 1 of 3

### OBAGI HYDRAFACTOR BROAD SPECTRUM SPF 30

sunscreen lotion

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EPERUA FALCATA BARK (UNII: L43J05M2KO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UBIDECARENONE (UNII: EJ27X76M46)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		75 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		

## Part 2 of 3

**OBAGI RETINOL 0.5**

night

### Product Information

Route of Administration TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	STEARYL ALCOHOL (UNII: 2KR8914H1Y)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	SAFFLOWER OIL (UNII: 65UEH262IS)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	SORBITOL (UNII: 506T60A25R)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### 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
Cosmetic			

## Part 3 of 3

### OBAGI EXFOLIATING CLEANSER

other personal cleanliness products

## Product Information

Route of Administration	TOPICAL
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## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
INGR	SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CHLORPHENESIN (UNII: I670DAL4SZ)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	PAPAIN (UNII: A236A06Y32)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		150 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			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/08/2015	

**Labeler** - OMP, Inc. (790553353)

## Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-580) , LABEL(62032-580) , PACK(62032-580) , ANALYSIS(62032-580)

Revised: 9/2019

OMP, Inc.