

OBAGI-C FX SYSTEM NORMAL-OILY SKIN BRIGHTENING SYSTEM WITH ARBUTIN- homosalate, octisalate, zinc oxide
Obagi Cosmeceuticals LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Obagi-C® Fx System Normal-Oily Skin Brightening System with Arbutin
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, 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

OBAGI®
MEDICAL

OBAGI-C® F X SYSTEM

Complete skin care system specially formulated for normal to oily skin that includes arbutin-based skin brighteners.

NORMAL OILY
Skin Brightening System with Arbutin

OBAGI[®]
MEDICAL

OBAGI-C[®] FX SYSTEM

Complete skin care system specially formulated for normal to oily skin that includes arbutin-based skin brighteners.



NORMAL OILY

Skin Brightening System with Arbutin

C-Cleansing Gel

6 fl. oz. (177 mL)

Directions: Use twice daily, morning and evening. Apply to damp face and neck with moistened fingertips, rub in circular motion and rinse completely with lukewarm water.

Ingredients: Water (Aqua), Sodium Laureth Sulfate, Sodium Lauroyl Oat Amino Acids, Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Sodium Chloride, Methylparaben, Glycerin, Saponins, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben, Xanthan Gum, Borago Officinalis Extract, Medicago Sativa (Alfalfa) Extract, Ascorbic Acid, Chamomilla Recutita (Matricaria) Flower Extract, Fragrance (Parfum), Red 33 (CI 17200), Yellow 5 (CI 19140)

C-Balancing Toner

6.7 fl. oz. (198 mL)

Directions: Use twice daily, in the morning and evening after cleansing. Pump a small amount (3 to 4 pumps) onto a cotton pad and gently wipe over entire face. Let air dry. Do not rinse.

Ingredients: Water (Aqua), Hamamelis Virginiana (Witch Hazel) Water, Propylene Glycol, Sodium PCA, Benzalkonium Chloride, Aloe Barbadensis Leaf Juice, Maltodextrin, Panthenol, Polyquaternium-10, Phenoxyethanol, Methylparaben

Fx C-Clarifying Serum (Skin Brightening Serum)

1 fl. oz. (30 mL)

Directions: Use once daily, in the morning. Apply 5 to 7 drops to the entire face, or as directed by your skin care physician. Massage in gently.

Ingredients: Water (Aqua), Propylene Glycol, Alcohol Denat., Dipropylene Glycol, Ascorbic Acid, Arbutin, Propylene Carbonate, Sodium Lauryl Sulfate
US patent 6,299,889

Fx C-Therapy Night Cream (Skin Brightener)

Net wt. 2 oz. (57 g)

Directions: Use daily in the evening. Dispense a small amount (approximately 1 to 2 pea-size drops) and apply to the entire face. Massage in gently.

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Ingredients: Water (Aqua), Glycerin, Cetyl Alcohol, Arbutin, PPG-2 Myristyl Ether Propionate, Sodium Lauryl Sulfate, TEA-Salicylate, Tocopheryl Acetate, Ascorbic Acid, Lactic Acid, Phenyl Trimethicone, Sodium Metabisulfite, BHT, Saponins, Disodium EDTA, Methylparaben, Propylparaben
US patent 9,168,398

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

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Made in USA with US and imported components.

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OBAGI-C[®] FX SYSTEM

Complete skin care system specially formulated for normal to oily skin that includes arbutin-based skin brighteners.

C-Cleansing Gel | AM+PM

Helps clarify and prepare your skin for the system's product ingredients, while also removing makeup and oil.

C-Balancing Toner | AM+PM

Specifically formulated for normal to oily skin, the C-Balancing Toner adjusts your skin's pH balance. As an essential step after cleansing, this alcohol-free, non-drying toner removes impurities and dead skin to prepare the skin for the next step in your skin care regimen.

Fx C-Clarifying Serum (Skin Brightening Serum) | AM

Skin brightening serum formulated with arbutin and L-ascorbic acid to help minimize the appearance of skin aging for a brighter complexion.

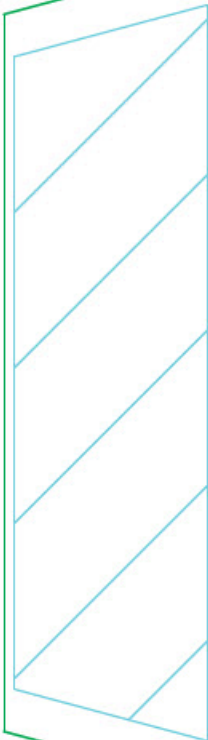
Fx C-Therapy Night Cream (Skin Brightener) | PM

This night cream is specially formulated with arbutin, antioxidants and an exfoliant to help diminish signs of skin aging and provide Vitamins C and E during the skin's nightly renewal process.

Sun Shield Matte Broad Spectrum SPF 50 | AM

Obagi Nu-Derm[®] sunscreen combines UVB absorption and UVA protection in an elegant, matte finish that is non-comedogenic and dermatologist tested. Sheer and fragrance free for all skin types.

OBAGI[®]
MEDICAL



Sun Shield Matte Broad Spectrum SPF 50
Net wt. 3 oz. (85 g)

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 <i>Directions</i>), 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	

Drug Facts (continued)	
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, Polymethylsiloxane, Sorbitan Olivatate, Silica, Polyglyceryl-6 Polytricholeate, 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	

Store at controlled room temperature 15°–25°C (59°–77°F).
FOR ALL PRODUCTS
Warnings: Avoid getting into eyes.
If product gets into the eyes, thoroughly rinse with water.
For external use only. Keep out of reach of children.

OBAGI-C FX SYSTEM NORMAL-OILY SKIN BRIGHTENING SYSTEM WITH ARBUTIN

homosalate, octisalate, zinc oxide kit

Product Information					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:62032-917
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:62032-917-01	1 in 1 CARTON	06/25/2021	06/25/2025	
Quantity of Parts					
Part #	Package Quantity		Total Product Quantity		
Part 1	1 BOTTLE, GLASS		30 mL		
Part 2	1 BOTTLE, PLASTIC		57 g		
Part 3	1 TUBE		85 g		
Part 4	1 BOTTLE, PLASTIC		177 mL		
Part 5	1 BOTTLE, PLASTIC		198 mL		
Part 1 of 5					
FX SYSTEM C-CLARIFYING SERUM SKIN BRIGHTENING SERUM					
cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid					
Product Information					
Route of Administration		TOPICAL			
Other Ingredients					
Ingredient Kind		Ingredient Name		Quantity	
INGR		PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
INGR		WATER (UNII: 059QF0KO0R)			
INGR		ASCORBIC ACID (UNII: PQ6CK8PD0R)			
INGR		SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
INGR		PROPYLENE CARBONATE (UNII: 8D08K3S51E)			
INGR		ALCOHOL (UNII: 3K9958V90M)			
INGR		DIPROPYLENE GLYCOL (UNII: E107L85C40)			
INGR		ARBUTIN (UNII: C5INA23HXF)			
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		1 in 1 CARTON			
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2010	

Part 2 of 5

FX SYSTEM C-THERAPY NIGHT SKIN BRIGHTENER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] cream

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
INGR	TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	ARBUTIN (UNII: C5INA23HXF)	
COLR	WHITE ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g 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		01/01/2004	

Part 3 of 5

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
C15-19 ALKANE (UNII: CI87N1IM01)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-140-09	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 DRUG	M020	12/02/2019	

Part 4 of 5

C-CLEANSING

other skin care preparations, leave-on [skin care preparations (creams, lotions, powder, and sprays)] gel

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	MEDICAGO SATIVA WHOLE (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	BORAGE (UNII: PB618V0K2W)	
COLR	ORANGE ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		177 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		01/01/2004	

Part 5 of 5

C-BALANCING TONER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
INGR	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	POLYQUATERNIUM-10 (400 MPA.S AT 2%) (UNII: HB1401PQFS)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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		01/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/02/2019	

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

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		118417470	PACK(62032-917) , LABEL(62032-917)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-917)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Packaging Systems, Inc. (DBA Paklab)		177711082	MANUFACTURE(62032-917)

Revised: 1/2026

Obagi Cosmeceuticals LLC