

OBAGI-C FX SYSTEM NORMAL-DRY SKIN BRIGHTENING SYSTEM WITH ARBUTIN-homosalate, octisalate, and 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-DRY SKIN BRIGHTENING SYSTEM WITH ARBUTIN

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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 Oliviate, Silica, Polyglyceryl-6 Polyrininoate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Questions or comments ?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

OBAGI®
MEDICAL

OBAGI-C® FX SYSTEM

NORMAL DRY

Skin Brightening System
with Arbutin

OBAGI[®] MEDICAL

NORMAL DRY

OBAGI[®] MEDICAL

OBAGI-C[®] FX SYSTEM

NORMAL DRY

Skin Brightening System with Arbutin

OBAGI[®] MEDICAL

NORMAL DRY

Skin Brightening System with Arbutin

NORMAL DRY



1 oz. (30 mL) AM

10% L-ascorbic acid to help minimize the appearance of sun-damaged skin.

Obagi-C leads by in the evening. Depresses a melanin (pigment) by 1 to 2 per-centage drop and apply to the entire face. Massage gently.

Wear sunglasses and eye drops to the entire face, or as directed by your skin care professional. Massage gently.

Wear sunglasses and eye drops to the entire face, or as directed by your skin care professional. Massage gently.

Keep out of reach of children.

Ingredients: water (aqua), glycerin, sodium butyrate, sodium ascorbate, L-ascorbic acid, arbutin, propylene glycol, sodium butyrate.

US Patent 6,299,899

C-Esterling Day Lotion 2 fl. oz. (59 mL) AM

A restorative, lightweight moisturizer that hydrates and gently exfoliates the skin to reveal a brighter, healthier-looking complexion.

Directions: Use once daily in the morning. Squash a small amount (approximately 1 to 2 per-centage drops) on to your hands. Using your fingertips, apply evenly to the entire face.

Massage gently until completely absorbed.

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.

Travel Bag Enclosed

US Patent 6,299,899

Ingredients: water (aqua), glycerin, sodium butyrate, sodium ascorbate, L-ascorbic acid, arbutin, propylene glycol, sodium butyrate.

US Patent 6,299,899

Keep out of reach of children.

Warnings: Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with water. For external use only.

Wash hands thoroughly with soap and water before and after use.

Directions: Use once daily in the morning. Squash a small amount (approximately 1 to 2 per-centage drops) on to your hands. Using your fingertips, apply evenly to the entire face.

Massage gently until completely absorbed.

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.

Ingredients: water (aqua), glycerin, sodium butyrate, sodium ascorbate, L-ascorbic acid, arbutin, propylene glycol, sodium butyrate.

US Patent 6,299,899

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US Patent 6,299,899

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US Patent 6,299,899

Keep out of reach of children.

Warnings: Avoid getting into eyes. If product gets into the eyes, thoroughly rinse with water. For external use only.

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Directions: Use once daily in the morning. Squash a small amount (approximately 1 to 2 per-centage drops) on to your hands. Using your fingertips, apply evenly to the entire face.

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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.

Ingredients: water (aqua), glycerin, sodium butyrate, sodium ascorbate, L-ascorbic acid, arbutin, propylene glycol, sodium butyrate.

US Patent 6,299,899

Keep out of reach of children.

Product information box containing barcode, lot number, expiration date, and contact information for Obagi Medical.

OBAGI-C[®] FX SYSTEM
1 oz. (30 mL) AM
10% L-ascorbic acid to help minimize the appearance of sun-damaged skin. Obagi-C leads by in the evening. Depresses a melanin (pigment) by 1 to 2 per-centage drop and apply to the entire face. Massage gently. Wear sunglasses and eye drops to the entire face, or as directed by your skin care professional. Massage gently. 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. Ingredients: water (aqua), glycerin, sodium butyrate, sodium ascorbate, L-ascorbic acid, arbutin, propylene glycol, sodium butyrate. US Patent 6,299,899



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

homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-537
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-537-58	1 in 1 CARTON	12/02/2019	

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	57 mL

Part 1 of 5

OBAGI -C FX SYSTEM C-CLARIFYING SERUM SKIN BRIGHTENING SERUM

lotions, oils, powders, and creams liquid

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	ARBUTIN (UNII: C5INA23HXF)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	

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		01/01/2004	

Part 2 of 5

OBAGI -C FX SYSTEM C-THERAPY NIGHT SKIN BRIGHTENER

night cream

Product Information

Route of Administration TOPICAL

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	METHYL PARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC10H)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	ARBUTIN (UNII: C5INA23HXF)	

Product Characteristics

color	WHITE	C48325
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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**OBAGI C- FX SYSTEM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN**

homosalate, octisalate, and zinc oxide lotion

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	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: 059QF0K00R)	
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: C187N1M01)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Polyglyceryl-2 Isostearate (UNII: 7B8OE71MQC)	
Sorbitan Olivatate (UNII: MDL271E3GR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Candelilla Wax (UNII: WL0328HX19)	
Yellow Wax (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUOXANE (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		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 FINAL	part352	12/02/2019	

OBAGI -C FX SYSTEM C-CLEANSING

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

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYLPARABEN (UNII: 3QP1IU3FV8)	
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	ALFALFA (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	BORAGE (UNII: PB618V0K2W)	

Product Characteristics

color ORANGE C48331

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

OBAGI -C FX SYSTEM C-EXFOLIATING DAY

moisturizing lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ETHYL PARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYL PARABEN (UNII: 3QP11U3FV8)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC1OH)	
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	SQUALANE (UNII: GW89575KF9)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
INGR	PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
INGR	PEG-8 RICINOLEATE (UNII: DM36F4D2OU)	
INGR	GLYCOLIC ACID (UNII: 0WT12SX38S)	
INGR	ARGININE (UNII: 94ZLA3W45F)	
INGR	ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	STEARETH-2 (UNII: V56DFE46J5)	
INGR	ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	EDETATE SODIUM (UNII: MP1J8420LU)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

color WHITE C48325

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 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		01/02/2004	

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
Universal Packaging Systems, Inc. DBA: PakLab		790530976	MANUFACTURE(62032-537) , LABEL(62032-537) , PACK(62032-537)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-537)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-537) , REPACK(62032-537)

Revised: 10/2019

Obagi Cosmeceuticals LLC