

**OBAGI-C RX SYSTEM NORMAL-OILY SKIN INTERVENTION- hydroquinone, octinoxate and zinc oxide
OMP, INC.**

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® RX SYSTEM NORMAL-OILY
SKIN INTERVENTION KIT**

C-Cleansing Gel 6 fl. oz. (177 mL.) AM+PM

A gel-based facial cleanser that clarifies and prepares your skin for absorption of the system's product ingredients. This concentrated cleanser gently removes excess oil, makeup, and other everyday impurities, and rinses clean, leaving your skin feeling fresh and clear.

Directions

Use twice daily, morning and evening. Massage a small amount of cleanser and lukewarm water onto skin, rubbing gently in a circular motion. Rinse completely 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), sodium laureth sulfate, sodium lauroyl oat amino acids, cocamidopropyl betaine, aloe barbadensis leaf juice (aloe barbadensis), ascorbic acid, glycerin, medicago sativa (alfalfa) extract, borago officinalis extract, chamomilla recutita (matricaria) flower extract (chamomilla recutita extract), sodium chloride, saponins, xanthan gum, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

C-Balancing Toner 6.7 fl. oz. (198 mL.) 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 thoroughly removes impurities and dead skin cells to prepare the skin for the next step in your skin care regimen. s.

Directions

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

Warnings

Avoid getting into eyes. **For external use only.**

Keep out of reach of children.

Ingredients

water (aqua), hamamelis virginiana (witch hazel) water, propylene glycol, sodium pca, benzalkonium chloride, aloe barbadensis leaf juice (aloe barbadensis), panthenol, polyquaternium-10, phenoxyethanol, methylparaben

C-Clarifying Serum Normal to Oily (Skin Lightening Serum) NDC 62032-122-10 1 fl. oz. (30 mL.) Hydroquinone USP, 4% Rx Only AM

Antioxidant serum containing Vitamin C and prescription-strength hydroquinone. This patented formulation for normal to oily skin reduces the appearance of dark spots for a lighter, brighter complexion.

Indications and usage

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation.

Dosage and administration

Use once daily in the morning. Apply 5-7 drops to the entire face, or as directed by your skin care physician. Massage in gently. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Warnings

Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

Each gram of Obagi-C Rx C-Clarifying Serum Normal to Oily contains:

Active Ingredient

Hydroquinone USP, 4% (40 mg/g)

Inactive Ingredients

water, propylene glycol, alcohol denat., dipropylene glycol, ascorbic acid, propylene carbonate, sodium lauryl sulfate, fragrance

See enclosed Package Insert for full prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

C-Therapy Night Cream (Skin Lightener) NDC 62032-105-36 Net wt. 2 oz. (57 g.) Hydroquinone USP, 4% Rx Only PM

A rich moisturizer that works while you sleep to renew and rejuvenate your skin. The C-Therapy Night Cream is uniquely formulated with prescription-strength hydroquinone to gradually diminish the appearance of dark spots and delivers Vitamins C and E during the skin's nightly renewal process.

Indications and usage

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation.

Dosage and Administration

Use daily in the evening. Dispense a small amount (approximately 1-2 pea-sized drops) and apply to the entire face. Massage in gently. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Warnings

Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

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.

Each gram of Obagi-C Rx C-Therapy Night Cream contains:

Active Ingredient

Hydroquinone USP, 4% (40 mg/g)

Inactive Ingredients

water, glycerin, cetyl alcohol, PPG-2 myristyl ether propionate, sodium lauryl sulfate, TEA-salicylate, lactic acid, phenyl trimethicone, tocopheryl acetate, sodium metabisulfite, ascorbic acid, methylparaben, disodium EDTA, propylparaben, saponins, BHT

See enclosed Package Insert for full prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Travel Bag and Patient Instruction Guide

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

This sunscreen combines UVB absorption and UVA protection in an elegant, matte finish that is non-comedogenic, allergy tested, and dermatologist tested. Sheer, PABA free, and fragrance free for all skin types.

Drug Facts

Active ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 10.5%	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

1,2-hexanediol, caprylyl glycol, cetareth-20, cetaryl alcohol, chlorphenesin, citric acid, cyclopentasiloxane, dimethicone crosspolymer-3, disodium EDTA, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-10 dimethicone, PEG-40 stearate, pentylene glycol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tocopheryl acetate, tropolone, ubiquinone, water, xanthan gum

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).

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OBAGI.COM Made in USA 41502110Z 5021

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC # 62032-517-04

OBAGI®
MEDICAL

OBAGI-C® RX SYSTEM

NORMAL OILY

Skin Intervention Kit

OBAGI-C® RX SYSTEM

An advanced system that offers the benefits of both prescription-strength 4% hydroquinone and Vitamin C to help correct early signs of skin aging, and maintain younger-looking skin.



C-Clearing Serum Normal to Oily Skin Lightening

Hydroquinone, Vitamin C, and Retinol. The combination of these three ingredients is a powerful skin-lightening system. Hydroquinone is a prescription-strength skin-lightening agent. Vitamin C is a powerful antioxidant and brightening agent. Retinol is a prescription-strength skin-renewing agent. The combination of these three ingredients is a powerful skin-lightening system.

C-Clearing Toner 4.7% (17.8 mL) 1AM-PM

Hydroquinone, Vitamin C, and Retinol. The combination of these three ingredients is a powerful skin-lightening system. Hydroquinone is a prescription-strength skin-lightening agent. Vitamin C is a powerful antioxidant and brightening agent. Retinol is a prescription-strength skin-renewing agent. The combination of these three ingredients is a powerful skin-lightening system.

C-Clearing Cream 4.7% (17.8 mL) 1AM-PM

Hydroquinone, Vitamin C, and Retinol. The combination of these three ingredients is a powerful skin-lightening system. Hydroquinone is a prescription-strength skin-lightening agent. Vitamin C is a powerful antioxidant and brightening agent. Retinol is a prescription-strength skin-renewing agent. The combination of these three ingredients is a powerful skin-lightening system.

C-Therapy Night Cream (Skin Lightener)

Hydroquinone, Vitamin C, and Retinol. The combination of these three ingredients is a powerful skin-lightening system. Hydroquinone is a prescription-strength skin-lightening agent. Vitamin C is a powerful antioxidant and brightening agent. Retinol is a prescription-strength skin-renewing agent. The combination of these three ingredients is a powerful skin-lightening system.

OBAGI-C® RX SYSTEM

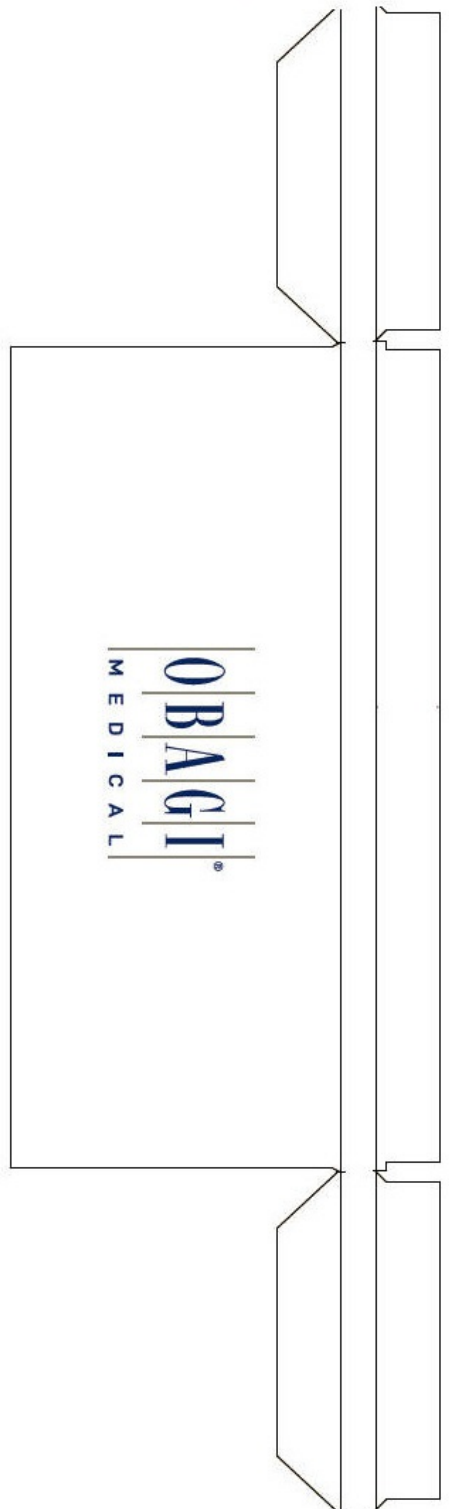
An advanced system that offers the benefits of both prescription-strength 4% hydroquinone and Vitamin C to help correct early signs of skin aging, and maintain younger-looking skin.

Sun Shield Matte Broad Spectrum SPF 50

UVA and UVB protection. Water-resistant. Sweat-resistant. Matte finish. Non-comedogenic. Fragrance-free. Paraben-free. Contains 5% Zinc Oxide and 3% Titanium Dioxide.

OBAGI-C® RX SYSTEM

An advanced system that offers the benefits of both prescription-strength 4% hydroquinone and Vitamin C to help correct early signs of skin aging, and maintain younger-looking skin.



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An advanced system that offers the benefits of both prescription-strength 4% hydroquinone and Vitamin C to help correct early signs of skin aging, and maintain younger-looking skin.

OBAGI-C RX SYSTEM NORMAL-OILY SKIN INTERVENTION

hydroquinone, octinoxate and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-517
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-517-04	1 in 1 CARTON		

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

OBAGI C RX SYSTEM C CLARIFYING SERUM

hydroquinone liquid

Product Information

Item Code (Source)	NDC:62032-122
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	

ALCOHOL (UNII: 3K9958V90M)

DIPROPYLENE GLYCOL (UNII: E107L85C40)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-122-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/2010	

Part 2 of 5

OBAGI-C RX SYSTEM C-THERAPY SKIN LIGHTENING WITH VITAMINS C AND E

hydroquinone cream

Product Information

Item Code (Source)	NDC:62032-105
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-105-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/2004	

Part 3 of 5

OBAGI-C RX SYSTEM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

octinoxate and zinc oxide lotion

Product Information

Item Code (Source)	NDC:62032-121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	105 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
WATER (UNII: 059QF0KO0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
PEG-40 STEARATE (UNII: ECU18C66Q7)
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
TROPOLONE (UNII: 7L6DL16P1T)
CHLORPHENESIN (UNII: I670DAL4SZ)
XANTHAN GUM (UNII: TTV12P4NEE)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
UBIDECARENONE (UNII: EJ27X76M46)
EDETATE DISODIUM (UNII: 7FLD91C86K)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)
SQUALANE (UNII: GW89575KF9)
POLYSORBATE 60 (UNII: CAL22UVI4M)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-121-90	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/07/2012	

Part 4 of 5

OBAGI-C RX SYSTEM C-CLEANSING WITH VITAMIN C
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	ETHYL PARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYL PARABEN (UNII: 3QP1U3FV8)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC1OH)	
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)	
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	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		177 mL in 1 BOTTLE, PLASTIC		

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 RX SYSTEM C-BALANCING TONER FOR NORMAL TO OILY SKIN

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

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	METHYL PARABEN (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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 mL in 1 BOTTLE, PLASTIC		

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		11/07/2012	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-517) , LABEL(62032-517) , PACK(62032-517)

Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-517) , LABEL(62032-517) , PACK(62032-517) , ANALYSIS(62032-517)

Establishment

Name	Address	ID/FEI	Business Operations
MILBAR LABORATORIES		195556790	MANUFACTURE(62032-517)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-517) , REPACK(62032-517)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-517)

Revised: 1/2013

OMP, INC.