

**NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION - 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](#).

**NU-DERM® SYSTEM NORMAL-OILY
SKIN TRANSFORMATION KIT**

Foaming Gel (Cleanser) 6.7 fl. oz. (198 mL.) AM+PM

A gel-based facial cleanser that transforms into a light and airy foam for a gentle daily cleansing experience. Formulated specially for normal to oily skin, the Nu-Derm Foaming Gel deep-cleans pores and removes makeup, dirt, and excess oil, leaving your skin feeling completely clean and ready for the next step of your skin care regimen.

Directions

Use twice daily, morning and evening. Wet hands and face. Work a small amount of cleanser into lather and massage 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), sodium laureth sulfate, sodium lauroyl oat amino acids, cocamidopropyl betaine, aloe barbadensis leaf juice (aloe barbadensis), medicago sativa (alfalfa) extract, borago officinalis extract, chamomilla recutita (matricaria) flower extract (chamomilla recutita extract), glycerin, sodium chloride, xanthan gum, saponins, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

Toner 6.7 fl. oz. (198 mL.) AM+PM

An essential step in your daily skin care routine, this alcohol-free, non-drying toner helps adjust your skin's pH for increased penetration of product ingredients. Use after cleansing to remove impurities and dead skin cells and to prepare the skin for hydration or appropriate products.

Directions

Use daily, in the morning and evening after cleansing. Saturate a cotton pad and gently wipe over entire face. 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, aloe barbadensis leaf juice (aloe barbadensis), potassium alum, sodium PCA, panthenol, DMDM hydantoin, polysorbate 80, allantoin, glycerin, salvia officinalis (sage) leaf extract (salvia officinalis), borago officinalis extract, calendula officinalis flower extract (calendula officinalis), saponins, iodopropynyl butylcarbamate, fragrance (parfum), blue 1 (CI 42090)

**Clear (Skin Bleaching and Corrector Cream) NDC 62032-101-36 Net wt. 2 oz. (57 g.)
Hydroquinone USP, 4% Rx Only AM+PM**

Dark spots may appear on the surface of your skin, but they actually start deep within the skin's layers. This gentle yet effective formula absorbs into the layers of your skin to deliver prescription-strength hydroquinone, helping to correct the appearance of age and sun spots for a healthier, more even complexion.

Indications and usage

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

Dosage and administration

Use daily, in the morning and evening. Squeeze a small amount (approximately 1-2 pea-sized amounts) onto your hand. Apply evenly to the entire face, extending to the hairline, over the ears, and ending with a feathering motion, or as directed by your physician. 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 Nu-Derm Clear contains:

Active ingredient

Hydroquinone USP, 4% (40 mg/g)

Inactive ingredients

water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, lactic acid, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, propylparaben, saponins, butylparaben

See enclosed Package Insert for full prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Exfoderm[®] Forte (Exfoliation Enhancer) Net wt. 2 oz. (57 g.) AM

A lightweight lotion that exfoliates the top layer of skin, removing dull, old skin cells while promoting new skin cells for a revitalized, healthy-looking complexion. Specifically developed for normal to oily skin that may need more exfoliation, this skin-enhancing formula contains alpha-hydroxy acids (glycolic acid, lactic acid) to help smooth roughness and reveal your skin's radiance.

Directions

Use daily, in the morning. Squeeze a small amount (approximately 1-2 pea-sized drops) onto your hands. Using your fingertips, apply evenly to the entire face. Massage until completely absorbed.

Warnings

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

Keep out of reach of children.

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.

Ingredients

water (aqua), triethanolamine, glycerin, glycolic acid, lactic acid, cetearyl alcohol, polysorbate 60, caprylic/capric triglyceride, emu oil (dromiceius oil), stearic acid, cetyl alcohol, stearyl alcohol, dimethicone, saponins, methylparaben, propylparaben

Hydrate (Facial Moisturizer) Net wt. 1.7 oz. (48 g.) AM+PM

A multi-action moisturizer with Hydromanil, a natural moisturizing agent derived from tara seed known to gradually deliver moisture to the skin. Also contains shea butter, mango butter, avocado and glycerin to help combat skin dryness. Suitable for all skin types.

Warnings

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

Keep out of reach of children.

Ingredients

water (aqua), glycerin, caprylic/capric triglyceride, butyrospermum parkii (shea) butter, cyclopentasiloxane, glyceryl stearate, cetyl alcohol, dimethicone, saccharide isomerate, stearic acid, polysilicone-11, glycine soja (soybean) sterols, persea gratissima (avocado) oil, mangifera indica (mango) seed butter, hydrolyzed caesalpinia spinosa gum, caesalpinia spinosa gum, hydrolyzed soybean fiber, sodium stearyl glutamate, caprylyl glycol, bisabolol, allantoin, tocopherol, tetrahydrodiferuloylmethane, panthenol, carbomer, hexylene glycol, sodium hydroxide, laureth-12, ethylhexylglycerin, phenoxyethanol

Blender® (Skin Lightener and Blending Cream) NDC 62032-100-36 Net wt. 2 oz. (57 g.) Hydroquinone USP, 4% Rx Only PM

A unique formula containing prescription-strength hydroquinone for the gradual lightening of sun spots, age spots, and other types of hyperpigmentation (discoloration). Specially formulated to optimize the delivery of product ingredients in the Nu-Derm System, this skin lightener helps reduce the signs of

aging and correct uneven skin tone. May be used with Tretinoin Cream¹ or Refissa² as prescribed by a physician.

¹ Tretinoin cream is indicated for topical application in the treatment of acne vulgaris.

² Refissa [Tretinoin Cream, USP (Emollient) 0.05%] is indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs. REFISSA DOES NOT ELIMINATE WRINKLES, REPAIR SUN-DAMAGED SKIN, REVERSE PHOTOAGING, or RESTORE A MORE YOUTHFUL or YOUNGER DERMAL HISTOLOGIC PATTERN.

Indications and usage

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation. Specially formulated for blending purposes as part of the Obagi Nu-Derm System.

Dosage and administration

Use daily, in the evening. Squeeze a small amount (approximately 1-2 pea-sized drops) onto your hand. Apply evenly to the entire face, or as directed by your skin care physician. 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 Nu-Derm Blender 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.

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

Travel Bag and Patient Instruction Guide

Store at controlled room temperature 15°C–25°C (59°F–77°F).

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PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 62032-513-00

**OBAGI®
MEDICAL**

NU-DERM® SYSTEM

NORMAL OILY

Skin Transformation Kit

NU-DERM® SYSTEM

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NU-DERM® SYSTEM

NORMAL OILY
Skin Transformation Kit

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MEDICAL



The #1 prescription-strength, physician-dispensed
skincare system that transforms cellular functions
at all layers of the skin, helping to make skin
look and act younger and healthier.

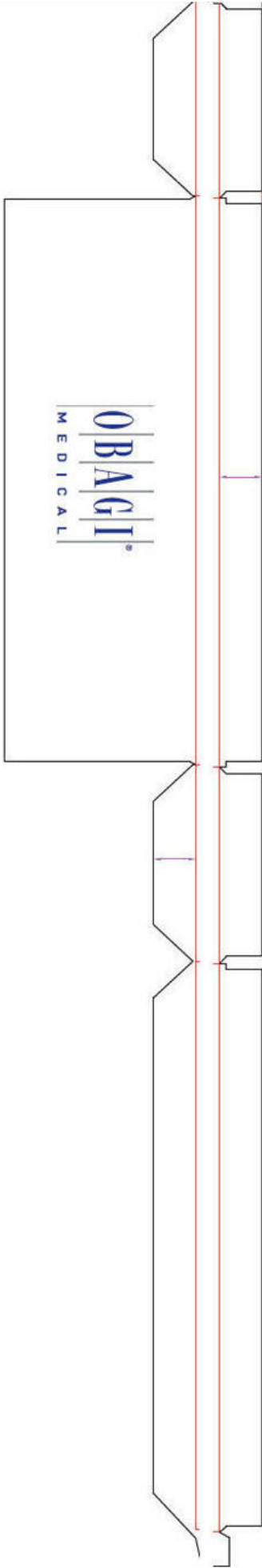
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NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION

hydroquinone, octinoxate, and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-513
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-513-00	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	57 g
Part 2	1 BOTTLE, PLASTIC	57 g
Part 3	1 TUBE	85 g
Part 4	1 BOTTLE, PLASTIC	198 mL
Part 5	1 BOTTLE, PLASTIC	198 mL
Part 6	1 BOTTLE, PLASTIC	57 g
Part 7	1 BOTTLE, PLASTIC	48 g

Part 1 of 7

NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information

Item Code (Source)	NDC:62032-100
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Route of Administration	TOPICAL
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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 HYDROXY TOLUENE (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:62032-100-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

Part 2 of 7

NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

hydroquinone cream

Product Information

Item Code (Source)	NDC:62032-101
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)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-101-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

Part 3 of 7

NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

octinoxate and zinc oxide lotion

Product Information

Item Code (Source)	NDC:62032-104
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:62032-104-90	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 7

NU-DERM FOAMING

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	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLPARABEN (UNII: 3QPIU3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
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	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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		01/01/1988	

Part 5 of 7

NU-DERM TONER

face and neck (excluding shaving preparations) liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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		01/01/1988	

Part 6 of 7

NU-DERM EXFODERM FORTE

face and neck (excluding shaving preparations) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC1OH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
INGR	GLYCOLIC ACID (UNII: 0WT12SX38S)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	EMU OIL (UNII: 344821WD61)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1988	

Part 7 of 7

NU-DERM HYDRATE FACIAL MOISTURIZER

face and neck (excluding shaving preparations) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	LAURETH-12 (UNII: OAH19558U1)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
INGR	SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color WHITE Score

Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/07/2012	

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
MILBAR LABORATORIES		195556790	MANUFACTURE(62032-513)

Establishment			
Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-513) , LABEL(62032-513) , PACK(62032-513)

Establishment			
Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-513) , LABEL(62032-513) , PACK(62032-513) , ANALYSIS(62032-513)

Establishment			
Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-513)

Establishment			
Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-513) , REPACK(62032-513)