

**ROSACLEAR SYSTEM- metronidazole
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](#).

ROSACLEAR® SYSTEM

**Gentle Cleanser
6.7 fl. oz. (198 mL)**

Gentle Cleanser provides gentle yet effective cleansing and instantly dissolves excess oil, makeup, and other everyday impurities.

Ingredients

water (aqua), cocamidopropyl betaine, glycerin, aloe barbadensis leaf juice, sodium lauroyl oat amino acids, sodium laureth sulfate, sodium chloride, glycereth-7, prunus armeniaca (apricot) kernel oil, borago officinalis extract, salvia officinalis (sage) leaf extract, acrylates/C10-30 alkyl acrylate crosspolymer, panthenol, oleyl lactate, saponins, citric acid, tetrasodium EDTA, triethanolamine, ethoxydiglycol, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), Yellow 5 (CI 19140)

**Metronidazole Topical Gel USP, 0.75%
NDC 62032-123-65 Net wt. 45 g**

Metronidazole Topical Gel USP, 0.75% is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.

Each gram contains

7.5 mg of metronidazole, USP as the active ingredient with 0.8 mg of methylparaben, NF and 0.2 mg of propylparaben, NF as preservatives in a gel consisting of carbopol 980, NF; edetate disodium, USP; propylene glycol, USP; purified water, USP; and sodium hydroxide, NF

**FOR TOPICAL USE ONLY (NOT FOR OPHTHALMIC USE).
RX ONLY.**

Store at 20°C–25°C (68°F–77°F) [see USP Controlled Room Temperature].

KEEP OUT OF REACH OF CHILDREN.

**Hydrating Complexion Corrector
Net wt. 3 oz. (85 g)**

Hydrating Complexion Corrector is formulated for sensitive skin and skin prone to flushing, redness, and blotchiness. Daily use of the product will help reduce the appearance of redness.

Ingredients

water (aqua), titanium dioxide (CI 77891), isohexadecane, coco-caprylate/caprate, ethylhexyl palmitate, dipropylene glycol, PEG-6, propylene glycol, stearyl alcohol, isocetyl behenate, glyceryl stearate, PEG-100 stearate, glycerin, talc, dimethicone, C13-15 alkane, allantoin, aloe barbadensis leaf juice, bacopa monniera extract, hydrolyzed oat protein, avena sativa (oat) beta glucan, avena sativa (oat) kernel

extract, sodium cocoyl amino acids, arnica montana flower extract, cupressus sempervirens seed extract, polygonatum multiflorum rhizome/root extract, glycyrrhiza glabra (licorice) root extract, lavandula angustifolia (lavender) flower/leaf/stem extract, sea whip extract (gorgonia extract), tocopheryl acetate, butylene glycol, ethylhexyl stearate, bisabolol, cetyl alcohol, polysorbate 60, sarcosine, pentylene glycol, hydroxyethylcellulose, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, magnesium aluminum silicate, xanthan gum, magnesium aspartate, potassium aspartate, potassium sorbate, diazolidinyl urea, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, alumina, silica, mica, iron oxides (CI 77491, CI 77492, CI 77499)

Store at controlled room temperature: 20°C–25°C (68°F–77°F). Do not freeze.

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www.obagi.com Made in USA 40726012Z 7260

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 62032-507-65

OBAGI®

MEDICAL

ROSACLEAR® SYSTEM

Gentle Cleanser

Metronidazole Topical Gel USP, 0.75% Rx Only

Hydrating Complexion Corrector

NDC# 67032-507-65



ROSACLEAR® SYSTEM

Gentle Cleanser
Metronidazole Topical Gel USP, 0.75% Rx Only
Hydrating Complexion Corrector

ROSACLEAR® SYSTEM





ROSACLEAR® SYSTEM

Rosacea is a skin condition characterized by a reddening of the cheeks, nose, chin, and/or forehead.

The Obagi® Rosaclear® System is a complete therapeutic system that gently and effectively reduces the symptoms associated with rosacea.

Gentle Cleanser 6.7 fl. oz. (198 mL)

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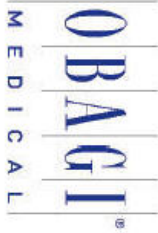
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ROSACLEAR® SYSTEM



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ROSACLEAR SYSTEM

metronidazole kit

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:62032-507

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-507-65	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	198 mL
Part 2	1 TUBE	85 g
Part 3	1 TUBE	45 g

Part 1 of 3

ROSACLEAR SYSTEM GENTLE CLEANSER

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: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	METHYLPARABEN (UNII: A2I8C7H9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLPARABEN (UNII: 3QPII1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	OLEYL LACTATE (UNII: B3AWW0N3GM)	
INGR	CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	

Product Characteristics

Color	YELLOW	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		01/01/2009	

Part 2 of 3

ROSACLEAR SYSTEM HYDRATING COMPLEXION CORRECTOR

face and neck (excluding shaving preparations) cream

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
INGR	POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
INGR	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
INGR	TALC (UNII: 7SEV7J4R1U)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	ALUMINUM OXIDE (UNII: LM26O6933)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	ISOHEXADECANE (UNII: 918X10UF1E)	
INGR	MICA (UNII: V8A1AW0880)	
INGR	FERRIC OXIDE RED (UNII: 1K09F3G675)	
INGR	FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	ETHYL PARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYL PARABEN (UNII: 3QP1U3FV8)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
INGR	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
INGR	COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INGR	CUPRESSUS SEMPERVIRENS SEED (UNII: V5M93EG3SN)	
INGR	POLYGONATUM MULTIFLORUM ROOT (UNII: EYW899536C)	
INGR	SARCOSINE (UNII: Z711V88R5F)	
INGR	POTASSIUM ASPARTATE (UNII: OC4598NZEQ)	
INGR	MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	ISOCETYL BEHENATE (UNII: JGD5498E0G)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	C13-15 ALKANE (UNII: 114P5I43UJ)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	OAT (UNII: Z6J799EAJK)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
INGR	GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2009	

Part 3 of 3

METRONIDAZOLE

metronidazole gel

Product Information

Item Code (Source)	NDC:62032-123
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METRONIDAZOLE (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)	METRONIDAZOLE	7.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-123-65	45 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077547	12/29/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		12/29/2012	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
TOLMAR PHARMACEUTICALS		79 1156578	MANUFACTURE(62032-507)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		6 119 216 69	MANUFACTURE(62032-507)

Revised: 3/2013

OMP, INC.