

CLENZIDERM M.D. SYSTEM ACNE THERAPEUTIC SYSTEM- salicylic acid and benzoyl peroxide

OBAGI COSMECEUTICAL LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**CLENZIDERM M.D.™ SYSTEM
ACNE THERAPEUTIC SYSTEM**

**Daily Care Foaming Cleanser
4 fl. oz. (118 mL) AM+PM**

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses

- for the treatment of acne
- dries up acne pimples
- helps prevent new acne pimples

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if

- irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Cleanse the entire affected area with a thin layer and rinse thoroughly one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other information

- Store away from heat and direct sunlight.

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

Inactive ingredients

butyl avocadate, cetyl hydroxyethylcellulose, chamomilla recutita (matricaria) flower extract, cocamidopropyl betaine, disodium EDTA, ethoxydiglycol, ext. violet 2, fragrance, glycerin, menthol, menthyl lactate, sodium laureth sulfate, sodium lauryl sulfate, water (aqua)

Questions or comments?

1.800.636.7546

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

Pore Therapy

5 fl. oz. (148 mL) AM+PM

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses

- for the treatment of acne
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Warnings

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Stop use and ask a doctor if

- irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Cleanse the skin thoroughly before applying this product.
- Shake product well before use.
- Place a cotton ball or pad over the pump well and pump 2 to 3 times to saturate, then cover the entire affected area with a thin layer one to three times daily.
- Allow the product to air-dry completely; do not rinse off.

- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day .

Other information

- Store away from heat and direct sunlight.
- Store at controlled room temperature: 15°C–25°C (59°F– 77°F).

Inactive ingredients

benzyl alcohol, chamomilla recutita (matricaria) flower extract, ethoxydiglycol, ext. violet 2, fragrance, glycerin, menthol, menthoxypropanediol, menthyl lactate, SD alcohol 40-B, water (aqua)

Questions or comments?

1.800.636.7546

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

Therapeutic Lotion

1.6 fl. oz. (47 mL) AM+PM

Drug Facts

Active ingredient

Benzoyl peroxide 5%

Purpose

Acne treatment

Uses

- for the treatment of acne
- dries up acne pimples
- helps prevent new acne pimples

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Do not use if you

- have very sensitive skin.

- are sensitive to benzoyl peroxide.

Stop use and ask a doctor if

- irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Cleanse the skin thoroughly before applying this product.
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

- Store away from heat and direct sunlight.
- Store at controlled room temperature: 15°C–25°C (59°F– 77°F).

Inactive ingredients

benzyl benzoate, BHT, dicaprylyl ether, dimethyl isosorbide, disodium EDTA, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, phenoxyethanol, polysorbate 60, propylene glycol, squalane, water (aqua)

Questions or comments?

1.800.636.7546

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

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

OBAGI®
MEDICAL

CLENZIderm M.D.™ SYSTEM

Acne Therapeutic System

This CLENZIderm M.D. SYSTEM includes:

- Daily Care Foaming Cleanser 4 fl. oz. (118 mL)
- Pore Therapy 5 fl. oz. (148 mL)
- Therapeutic Lotion 1.6 fl. oz. (47 mL)



CLENZiderm M.D.™ SYSTEM

Acne Therapeutic System

This CLENZiderm M.D. SYSTEM includes:

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CLENZiderm M.D.™ SYSTEM

A 3-step system that combines powerful acne-fighting medications to effectively treat existing acne and help prevent future breakouts.



Daily Care Foaming Cleanser 4 fl. oz. (118 mL) AM+PM

A light, foaming acne cleanser with 2% salicylic acid to help unclog pores and wash away dead skin cells and impurities, and cooling menthol, to leave skin feeling clean and refreshed.

Drug Facts

Active ingredient	Purpose
Salicylic acid 2%	Acne treatment

Uses ■ for the treatment of acne ■ dries up acne pimples
■ helps prevent new acne pimples

Warnings

For external use only

When using this product ■ skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if ■ irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Cleanse the entire affected area with a thin layer and rinse thoroughly one to three times daily. ■ Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other information ■ Store away from heat and direct sunlight. ■ Store at controlled room temperature: 15°C–25°C (59°F–77°F).

Inactive ingredients

butyl stearate, cetyl hydroxyethylcellulose, chamomilla recutita (matricaria) flower extract, cocamidopropyl betaine, disodium EDTA, ethoxydiglycol, ext. violet 2, fragrance, glycerin, menthol, methyl lactate, sodium laureth sulfate, sodium lauryl sulfate, water (aqua)

Questions or comments? 1.800.636.7546
Monday–Friday 9a.m.–4p.m. Pacific Time

Pore Therapy 5 fl. oz. (148 mL) AM+PM

Refreshing treatment that helps unclog and refine pores while clearing away dead skin cells with 2% salicylic acid.

Drug Facts

Active ingredient	Purpose
Salicylic acid 2%	Acne treatment

Uses ■ for the treatment of acne ■ dries up acne pimples
■ helps prevent new acne pimples

Warnings

For external use only

When using this product ■ skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if ■ irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Cleanse the skin thoroughly before applying this product. ■ Shake product well before use. ■ Place a cotton ball or pad over the pump well and pump 2 to 3 times to saturate, then cover the entire affected area with a thin layer one to three times daily. ■ Allow the product to air-dry completely; do not rinse off. ■ Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other information ■ Store away from heat and direct sunlight. ■ Store at controlled room temperature: 15°C–25°C (59°F–77°F).

Inactive ingredients

benzyl alcohol, chamomilla recutita (matricaria) flower extract, ethoxydiglycol, ext. violet 2, fragrance, glycerin, menthol, menthylpropanediol, methyl lactate, SD alcohol 40-B, water (aqua)

Questions or comments? 1.800.636.7546
Monday–Friday 9a.m.–4p.m. Pacific Time

Distributed by Obagi Cosmeceuticals LLC,
Lag Beach, CA 90806

All products/brand names, whether designated by notice or not

Therapeutic Lotion 1.6 fl. oz. (47 mL) AM+PM

Lightweight acne treatment lotion with 5% BPO uniquely formulated to clear acne.

Drug Facts

Active ingredient	Purpose
Benzoyl peroxide 5%	Acne treatment

Uses ■ for the treatment of acne ■ dries up acne pimples
■ helps prevent new acne pimples

Warnings

For external use only

When using this product ■ skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. ■ avoid unnecessary sun exposure and use a sunscreen. ■ avoid contact with the eyes, lips, and mouth. ■ avoid contact with hair and dyed fabrics, which may be bleached by this product. ■ skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Do not use if you ■ have very sensitive skin. ■ are sensitive to benzoyl peroxide.

Stop use and ask a doctor if ■ irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Cleanse the skin thoroughly before applying this product. ■ Cover the entire affected area with a thin layer one to three times daily. ■ Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ■ If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information ■ Store away from heat and direct sunlight. ■ Store at controlled room temperature: 15°C–25°C (59°F–77°F).

Inactive ingredients

benzyl benzoate, BHT, dicaprylyl ether, dimethyl isosorbide, disodium EDTA, hydroxyethyl acrylate/sodium acryloyldimethyl

Acne Therapeutic System



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www.obagi.com
US patents 7390431-1 and 7445729-1
Made in USA with U.S. and Imported components 9434402

taurate copolymer, phenylethanol, polysorbate 60, propylene glycol, squalane, water (aqua)

Questions or comments? 1.800.636.7546
Monday-Friday 9a.m.-4p.m. Pacific Time

CLENZiderm M.D.™ SYSTEM

Acne Therapeutic System



CLENZiderm M.D.™ SYSTEM

Acne Therapeutic System



CLENZIDERM M.D. SYSTEM ACNE THERAPEUTIC SYSTEM

salicylic acid and benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-613
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-613-01	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2012	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	118 mL
Part 2	1 BOTTLE, PLASTIC	148 mL
Part 3	1 BOTTLE, PLASTIC	47 mL

Part 1 of 3

CLENZIDERM DAILY CARE FOAMING CLEANSER ACNE TREATMENT

salicylic acid liquid

Product Information

Item Code (Source)	NDC:62032-610
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MENTHYL LACTATE, (-) (UNII: 2BF9E65L7D)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
WATER (UNII: 059QF0KO0R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
CHAMOMILE (UNII: FGL3685T2X)	
Glycerin (UNII: PDC6A3C0OX)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-610-04	118 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
OTC MONOGRAPH FINAL	part333D	02/01/2007	

Part 2 of 3

CLENZIDERM PORE THERAPY ACNE TREATMENT
salicylic acid liquid

Product Information

Item Code (Source)	NDC:62032-612
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MENTHYL LACTATE, (-) (UNII: 2BF9E65L7I)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
WATER (UNII: 059QF0KO0R)	
CHAMOMILE (UNII: FGL3685T2X)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-612-04	148 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
OTC MONOGRAPH FINAL	part333D	02/01/2007	

Part 3 of 3

CLENZIDERM THERAPEUTIC

benzoyl peroxide lotion

Product Information

Item Code (Source)	NDC:62032-611
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 mL
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Inactive Ingredients	
Ingredient Name	Strength
BENZYL BENZOATE (UNII: N863NB338G)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0K00R)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-611-01	47 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
OTC MONOGRAPH FINAL	part333D	07/01/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	01/01/2012	

Labeler - OBAGI COSMECEUTICAL LLC (790553353)

Establishment			
Name	Address	ID/FEI	Business Operations

G.S.COSMECEUTICAL USA, INC.		0170 14734	MANUFACTURE(62032-613)
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Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-613) , LABEL(62032-613) , PACK(62032-613)

Revised: 3/2019

OBAGI COSMECEUTICAL LLC