

CLEARASIL ULTRA ACNE SYSTEM- salicylic acid and benzoyl peroxide
Reckitt Benckiser 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.

Clearasil®
Ultra Acne Solution System

Step 1: StayClear® Daily Face Wash

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only

When using this product

- avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
- 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.
- limit use to the face and neck

Stop use and ask a doctor if skin or eye irritation develops

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- for best results, use twice daily. Use everyday in the morning and evening.
- wet face
- dispense 1 pump of wash into palm of hand
- add water and gently massage onto face, avoiding eye area
- rinse off thoroughly with warm water and pat dry
- 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 directed by a doctor
- if bothersome dryness or peeling occurs, reduce the application to once a day or every other day

Other information

- store in a cool, dry place

Inactive ingredients

water, PPG-15 stearyl ether, glycerin, stearyl alcohol, cetyl betaine, distearyldimonium chloride, sodium lauryl sulfate, oxidized polyethylene, cetyl alcohol, alcohol denat., steareth-21, sodium chloride, behenyl alcohol, PPG-30, steareth-2, fragrance, menthol, disodium EDTA, BHT

Step 2: StayClear® Daily Toner

Warnings

For external use only. Avoid contact with eyes and mouth. **If in eyes**, rinse eyes thoroughly with water. **If ingested**, rinse mouth thoroughly and drink a glass of water.

Stop use if skin irritation occurs. This lotion may not suit very dry skin.

Keep out of reach of children.

Directions

Use everyday in the morning and evening after Step 1. Moisten a cotton ball and smooth over cleansed face and neck, avoiding eye area. Do not rinse. Allow product to dry completely. Follow with application of Step 3.

Ingredients

water, alcohol denat., aloe barbadensis leaf juice, myrtrimonium bromide, cetareth-12, disodium cocoamphodiacetate, sodium chloride, allantoin, chlorhexidine digluconate, tartaric acid, imidazolidinyl urea, methylparaben, propylparaben

Step 3: StayClear® Daily Lotion

Drug Facts

Active ingredient

Salicylic acid 0.5%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only

When using this product

- avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
- 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 skin or eye irritation develops

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- clean 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

Other information

- store in a cool, dry place

Inactive ingredients

water, glyceryl polymethacrylate, isohexadecane, cyclomethicone, glycerin, butylene glycol, PEG-8, steareth-2, lauryl methacrylate/glycol dimethacrylate crosspolymer, propylene glycol, polyacrylamide, steareth-21, C13-14 isoparaffin, xanthan gum, laureth-7, fragrance, sodium hydroxide, tetrasodium EDTA, methylparaben, propylparaben

Rapid Action Treatment Cream

Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with eyes, lips, and mouth
- avoid contact with hair or dyed fabrics, which may be bleached by 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.
- 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.

Stop use and ask a doctor if irritation becomes severe

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- clean skin thoroughly before applying this product
- cover the entire effected area with a thin layer, one to three times 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 as a doctor.

Other information

- keep tightly closed
- store at controlled room temperature 68-77°F (20-25°C)

Inactive ingredients

water, gluconolactone, glyceryl stearate, glycerin, PEG-40 stearate, PEG-100 stearate, cetyl alcohol, dimethicone, magnesium aluminum silicate, xanthan gum, phenoxyethanol, ammonium hydroxide, isopropylparaben, arginine, isobutylparaben, butylparaben, titanium dioxide

Questions? Comments?

Call **1-866-25-CLEAR (1-866-252-5327)** You may also report side effects to this phone number.

Distributed by Reckitt Benckiser LLC
Parsippany, NJ 07054-0224

StayClear® Daily Face Wash made in France
StayClear® Daily Toner made in France
StayClear® Daily Lotion made in USA
Rapid Action Treatment Cream made in USA

PRINCIPAL DISPLAY PANEL - Kit Carton

Clearasil®

ULTRA

Acne Solution System

Up to

**100% fewer
breakouts**

in as little

as **4 weeks**

1 Step 1

StayClear® Daily Face Wash
Salicylic Acid 2% Acne Medication
5 FL OZ (150 mL)

2 Step 2

StayClear® Daily Toner

5 FL OZ (150 mL)

3 Step 3

StayClear[®] Daily Lotion

Salicylic Acid 0.5% Acne Medication

1.5 FL OZ (45 mL)

Also includes:

Rapid Action Treatment Cream

Benzoyl Peroxide 10% Acne Medication

NET WT 0.45 OZ (13 g)

Ink & Varnish Free Area

Clearasil®

Acne Solution System

ULTRA

Clearasil®

Acne Solution System

ULTRA

Up to
**100% fewer
breakouts**
in as little
as **4 weeks**



1 Step 1
StayClear® Daily Face Wash
Salicylic Acid 2% Acne Medication
5 FL OZ (150 mL)

2 Step 2
StayClear® Daily Toner
5 FL OZ (150 mL)

3 Step 3
StayClear® Daily Lotion
Salicylic Acid 0.5% Acne Medication
1.5 FL OZ (45 mL)

Also includes:
Rapid Action Treatment Cream
Benzoyl Peroxide 10% Acne Medication
NET WT 0.45 OZ (13 g)

Clearasil

ULTRA

Acne Solution System

In emergencies where you need to treat breakouts fast, use the *Rapid Action Treatment Cream* to visibly reduce redness and spot size in as little as 4 hours!

To maintain healthy-looking clear skin, use the 3-step regimen everyday.

- 1** *StayClear*® Daily Face Wash
Oil free, micro-bead cream formula with 2% Salicylic Acid gently exfoliates and deep cleans pores to help clear acne breakouts and prevent new ones from forming.
- 2** *StayClear*® Daily Toner
Fragrance-free formula revitalizes skin leaving it soothed and refreshed.
- 3** *StayClear*® Daily Lotion
Shine control moisturizing formula with 0.5% Salicylic Acid hydrates skin and helps prevent future acne breakouts.

StayClear® Daily Face Wash made in France
StayClear® Daily Toner made in France
StayClear® Daily Lotion made in USA
Rapid Action Treatment Cream made in USA

Step 1: *StayClear*® Daily Face Wash

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne medication

Use for the treatment of acne

Warnings

For external use only

When using this product

- avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
- 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. ■ limit use to the face and neck

Stop use and ask a doctor if skin or eye irritation develops

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- for best results, use twice daily. Use everyday in the morning and evening. ■ wet face
- dispense 1 pump of wash into palm of hand ■ add water and gently massage onto face, avoiding eye area
- rinse off thoroughly with warm water and pat dry
- 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 directed by a doctor
- if bothersome dryness or peeling occurs, reduce the application to once a day or every other day

Other information

- store in a cool, dry place

Inactive ingredients

water, PPG-15 stearyl ether, glycerin, stearyl alcohol, cetyl betaine, distearyldimonium chloride, sodium lauryl sulfate, oxidized polyethylene, cetyl alcohol, alcohol denat., steareth-21, sodium chloride, behenyl alcohol, PPG-30, steareth-2, fragrance, menthol, disodium EDTA, BHT

Step 2: *StayClear*® Daily Toner

Warnings

For external use only. Avoid contact with eyes and mouth. **If in eyes,** rinse eyes thoroughly with water. **If ingested,** rinse mouth thoroughly and drink a glass of water. Stop use if skin irritation occurs. This lotion may not suit very dry skin. **Keep out of reach of children.**

Directions

Use everyday in the morning and evening after Step 1. Moisten a cotton ball and smooth over cleansed face and neck, avoiding eye area. Do not rinse. Allow product to dry completely. Follow with application of Step 3.

Ingredients

water, alcohol denat., aloe barbadensis leaf juice, myrtrimonium bromide, ceteareth-12, disodium cocoamphodiacetate, sodium chloride, allantoin, chlorhexidine digluconate, tartaric acid, imidazolidinyl urea, methylparaben, propylparaben

Step 3: *StayClear*® Daily Lotion

Drug Facts

Active ingredient

Salicylic acid 0.5%

Purpose

Acne medication

Use for the treatment of acne

Warnings

For external use only

When using this product

- avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
- 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.

Ink & Varnish Free Area

Ink & Varnish
Free Area

Drug Facts (continued)

Stop use and ask a doctor if skin or eye irritation develops

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- clean 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

Other information

- store in a cool, dry place

Inactive ingredients

water, glyceryl polymethacrylate, isohexadecane, cyclomethicone, glycerin, butylene glycol, PEG-8, steareth-2, lauryl methacrylate/glycol dimethacrylate crosspolymer, propylene glycol, polyacrylamide, steareth-21, C13-14 isoparaffin, xanthan gum, laureth-7, fragrance, sodium hydroxide, tetrasodium EDTA, methylparaben, propylparaben

Rapid Action Treatment Cream

Drug Facts

Active ingredient	Purpose
Benzoyl peroxide 10%	Acne medication

Use for the treatment of acne

Warnings

For external use only

- Do not use** if you
- have very sensitive skin
 - are sensitive to benzoyl peroxide

When using this product

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with eyes, lips, and mouth
- avoid contact with hair or dyed fabrics, which may be bleached by 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.
- 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.

Stop use and ask a doctor if irritation becomes severe

Ink & Varnish
Free Area

Ink & Varnish
Free Area

Drug Facts (continued)

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- clean skin thoroughly before applying this product
- cover the entire effected area with a thin layer, one to three times 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

- keep tightly closed
- store at controlled room temperature 68-77°F (20-25°C)

Inactive ingredients

water, gluconolactone, glyceryl stearate, glycerin, PEG-40 stearate, PEG-100 stearate, cetyl alcohol, dimethicone, magnesium aluminum silicate, xanthan gum, phenoxyethanol, ammonium hydroxide, isopropylparaben, arginine, isobutylparaben, butylparaben, titanium dioxide

Questions? Comments? Call
1-866-25-CLEAR (1-866-252-5327)
You may also report side effects to this phone number.



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Ink & Varnish
Free Area

CLEARASIL ULTRA ACNE SYSTEM

salicylic acid and benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-362
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-362-00	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PUMP	150 mL
Part 2	1 BOTTLE	150 mL
Part 3	1 TUBE	45 mL
Part 4	1 TUBE	13 g

Part 1 of 4

CLEARASIL ULTRA STAYCLEAR DAILY FACE WASH

salicylic acid lotion

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
PPG-15 stearyl ether (UNII: 11118XLS1L)	
glycerin (UNII: PDC6A3C0OX)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
cetyl betaine (UNII: E945X08YA9)	
distearyldimonium chloride (UNII: OM9573ZX3X)	
sodium lauryl sulfate (UNII: 368GB5141J)	
cetyl alcohol (UNII: 936JST6JCN)	
steareth-21 (UNII: 53J3F32P58)	
sodium chloride (UNII: 451W47IQ8X)	

docosanol (UNII: 9G1OE216XY)	
steareth-2 (UNII: V56DFE46J5)	
menthol (UNII: L7T10EIP3A)	
edetate disodium (UNII: 7FLD91C86K)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		150 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2012	

Part 2 of 4

CLEARASIL ULTRA STAYCLEAR DAILY TONER

other skin care preparations solution

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0K00R)	
INGR	aloe vera leaf (UNII: ZY81Z83H0X)	
INGR	tetradonium bromide (UNII: 8483H94W1E)	
INGR	ceteareth-12 (UNII: 7V4MR24V5P)	
INGR	disodium cocoamphodiacetate (UNII: 18L9G3U51M)	
INGR	sodium chloride (UNII: 451W47IQ8X)	
INGR	allantoin (UNII: 344S277G0Z)	
INGR	chlorhexidine gluconate (UNII: MOR84MUD8E)	
INGR	tartaric acid (UNII: W4888I19H)	
INGR	imidurea (UNII: M629807ATL)	
INGR	methylparaben (UNII: A2I8C7HI9T)	
INGR	propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		150 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2012	

Part 3 of 4

CLEARASIL ULTRA STAYCLEAR DAILY

salicylic acid lotion

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
isohexadecane (UNII: 918X1OUF1E)	
cyclomethicone (UNII: NMQ347994Z)	
glycerin (UNII: PDC6A3C00X)	
butylene glycol (UNII: 3XUS85K0RA)	
polyethylene glycol 400 (UNII: B697894SGQ)	
steareth-2 (UNII: V56DFE46J5)	
lauryl methacrylate/glycol dimethacrylate crosspolymer (UNII: EX0F4CZ66H)	
propylene glycol (UNII: 6DC9Q167V3)	
steareth-21 (UNII: 53J3F32P58)	
C13-14 isoparaffin (UNII: E4F12ROE70)	
xanthan gum (UNII: TTV12P4NEE)	
laureth-7 (UNII: Z95S6G8201)	
sodium hydroxide (UNII: 55X04QC32I)	
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		45 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2012	

Part 4 of 4

CLEARASIL ULTRA RAPID ACTION VANISHING TREATMENT

benzoyl peroxide cream

Product Information

Item Code (Source)	NDC:63824-309
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
gluconolactone (UNII: WQ29KQ9POT)	
glyceryl monostearate (UNII: 230OU9XXE4)	
glycerin (UNII: PDC6A3C0OX)	
PEG-40 stearate (UNII: ECU18C66Q7)	
PEG-100 stearate (UNII: YD01N1999R)	
cetyl alcohol (UNII: 936JST6JCN)	
dimethicone (UNII: 92RU3N3Y1O)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
xanthan gum (UNII: TTV12P4NEE)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ammonia (UNII: 5138Q19F1X)	
isopropylparaben (UNII: A6EOX47QK0)	
arginine (UNII: 94ZLA3W45F)	
isobutylparaben (UNII: 0QQJ25X58G)	
butylparaben (UNII: 3QPII3FV8)	
titanium dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-309-02	13 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2012	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 11/2012

Reckitt Benckiser LLC