

CLEARASIL ULTRA RAPID ACTION CLEAR SKIN- 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™ Rapid Action Clear Skin

Drug Facts

Rapid Action Daily Face Wash

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 the eyes. If product gets into the 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

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

Directions

- wet face
- dispense product into hands and massage gently onto face and neck, avoiding the delicate eye area
- cover the entire affected area with a thin layer and rinse thoroughly with warm water 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
- do not freeze

Inactive ingredients

water, sodium cocoyl isethionate, cetearyl alcohol, glycerin, sodium laureth sulfate, sodium cocoamphoacetate, cocamidopropyl betaine, sodium hydroxide, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, disodium EDTA, Lavandula stoechas extract, Helichrysum italicum extract, Cistus monspeliensis extract

Rapid Action Pads**Active ingredient**

Salicylic acid 2%

Purpose

Acne medication

Use

for the treatment of acne

Warnings**For external use only**

Flammable keep away from extreme heat or open flame

When using this product

- avoid contact with the eyes. If product gets into the 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

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

Directions

- clean the skin thoroughly before applying this product
- wipe a pad over face and neck to cover the entire affected area with a thin layer 1 to 3 times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to 2 or 3 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

- keep jar lid tightly closed
- store in a cool, dry place but do not freeze

Inactive ingredients

water, alcohol denat., glycerin, isoceteth-20, sorbitol, sodium hydroxide, fragrance, Lavandula stoechas extract, Helichrysum italicum extract, Cistus monspeliensis extract, disodium EDTA

Rapid Action Vanishing Treatment Cream

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 or are sensitive to benzoyl peroxide

When using this product

- **avoid unnecessary sun exposure and use a sunscreen**
- avoid contact with the eyes, lips and mouth
- avoid contact with hair or dyed fabrics, including carpet and clothing which may be bleached by this product
- with other topical acne medications, at the same time or immediately following use of this product, increased dryness or irritation of the skin may occur. If this occurs, only one medication should be used unless directed by a doctor.
- skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. More frequent use or higher concentrations may aggravate skin irritation. Mild irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if skin irritation becomes severe

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- cleanse the skin thoroughly before applying medication
- 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, use a sunscreen.** Allow **Clearasil Ultra®** Rapid Action Vanishing Treatment Cream to dry, then follow directions on sunscreen labeling. If irritation or sensitivity develops, discontinue 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, butylparaben, isobutylparaben, arginine, titanium dioxide

Questions?

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

PRINCIPAL DISPLAY PANEL - Kit Carton

Clearasil[®]

ULTRA[™]

Rapid Action
Clear Skin Kit

MAXIMUM
STRENGTH

Visibly
clearer skin
in as little as
12 hours

- **Clearasil Ultra Rapid
Action Daily Face Wash
6.78 FL. OZ. (200 mL)**
- **Clearasil Ultra Rapid
Action Pads
90 Pads 3.58 in² (23.1 cm²)**
- **Clearasil Ultra Rapid
Action Treatment Cream
0.45 OZ. (13 g)**

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Action Treatment Cream
0.45 OZ. (13 g)

Drug Facts (Continued)

Other Information

- keep jar lid tightly closed
- store in a cool, dry place but do not freeze

Inactive Ingredients

water, alcohol denat., glycerin, isoceteth-20, sorbitol, sodium hydroxide, fragrance, Lavandula stoechas extract, Helichrysum italicum extract, Cistus monpetitanensis extract, disodium EDTA

Rapid Action Vanishing Treatment Cream

Active Ingredient	Purpose
Benzoyl Peroxide 10%	Acne medication

Use for the treatment of acne

Warnings

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When using this product

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- skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. More frequent use or higher concentrations may aggravate skin irritation. Mild irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if skin irritation becomes severe

Keep out of reach of children.

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Directions

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- 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 not suitable, use a sunscreen. Allow Clearasil Ultra[®] Rapid Action Vanishing Treatment Cream to dry, then follow directions on sunscreen labeling. If irritation or sensitivity develops, discontinue 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, phenylethanol, ammonium hydroxide, isopropylparaben, butylparaben, isobutylparaben, arginine, titanium dioxide

Questions?

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HEALTHY PERSONS FORM 1

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Clearasil®

ULTRA™

Clearasil Ultra® Skin Science provides you with the perfect assortment of Maximum Strength technologies to fight acne and breakouts.

Each of these products fight acne fast and begin working instantly to give you visibly clearer skin in as little as 12 hours. The Ultra Clear Skin Kit is made for usage at home and on-the-go.

- **Rapid Action Daily Face Wash**
Penetrates deep down into pores to fight pimples fast
- **Rapid Action Pads**
Exfoliates skin removing acne-causing bacteria to help prevent breakouts
- **Rapid Action Vanishing Treatment Cream**
Visibly reduces pimple size and redness in as little as 4 hours

Drug Facts

Rapid Action Daily Face Wash

Active Ingredient	Purpose
Salicylic acid 2%	Acne medication

Use for the treatment of acne

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Rapid Action Pads

Active Ingredient	Purpose
Salicylic acid 2%	Acne medication

Use for the treatment of acne

Warnings

For external use only

Flammable keep away from extreme heat or open flame

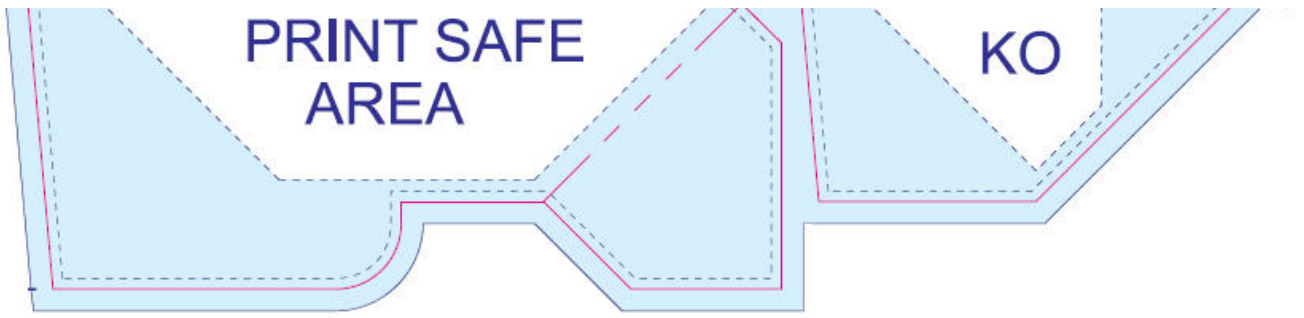
When using this product

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CLEARASIL ULTRA RAPID ACTION CLEAR SKIN

salicylic acid and benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-423
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-423-00	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	200 mL
Part 2	1 JAR	90
Part 3	1 TUBE	13 g

Part 1 of 3

CLEARASIL ULTRA RAPID ACTION DAILY FACE WASH

salicylic acid lotion

Product Information

Item Code (Source)	NDC:63824-380
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
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water (UNII: 059QF0KO0R)	
sodium cocoyl isethionate (UNII: 518XTE8493)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
glycerin (UNII: PDC6A3C0OX)	
sodium laureth-3 sulfate (UNII: BPV390UAP0)	
sodium cocoamphoacetate (UNII: W7Q5E87674)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
sodium hydroxide (UNII: 55X04QC32I)	
edetate disodium (UNII: 7FLD91C86K)	
lavandula stoechas flowering top (UNII: 70759G2U6A)	
helichrysum italicum flower (UNII: P62Y550X24)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-380-88	200 mL in 1 TUBE; 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	09/01/2014	

Part 2 of 3

CLEARASIL ULTRA RAPID ACTION PADS
salicylic acid solution

Product Information	
Item Code (Source)	NDC:63824-345
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	0.03 g

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	
glycerin (UNII: PDC6A3C0OX)	
isoceteth-20 (UNII: O020065R7Z)	
sorbitol (UNII: 506T60A25R)	

sodium hydroxide (UNII: 55X04QC32I)	
lavandula stoechas flowering top (UNII: 70759G2U6A)	
Helichrysum italicum flower (UNII: P62Y550X24)	
edetate disodium (UNII: 7FLD91C86K)	

Product Characteristics

Color		Score	
Shape	ROUND (Pad)	Size	231mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-345-01	90 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	06/01/2012	

Part 3 of 3

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)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
dimethicone (UNII: 92RU3N3Y1O)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
xanthan gum (UNII: TTV12P4NEE)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ammonia (UNII: 5138Q19F1X)	
isopropylparaben (UNII: A6EOX47QK0)	
butylparaben (UNII: 3QPII03FV8)	
isobutylparaben (UNII: 0QQJ25X58G)	
arginine (UNII: 94ZLA3W45F)	
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; 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	03/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/01/2015	

Labeler - Reckitt Benckiser LLC (094405024)