

**ACNE FREE SEVERE ACNE 24 HR ACNE CLEARING SYSTEM- benzoyl peroxide  
AcneFree, LLC**

-----  
**Acne Free SEVERE ACNE 24 HR Acne Clearing System KIT**

***Drug Facts***

***Active ingredient***

Benzoyl peroxide 2.5%

***Purpose***

Acne treatment

***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**

- 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.

**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 right away.

**Directions**

- use every morning and evening
- apply a dime-size amount to damp skin and gently massage, avoiding the eye area
- rinse well
- use wash on entire affected area one to two times daily
- because excessive drying of the skin may occur, start with washing once daily, then gradually increase to two times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce cleansing 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.
- may be used on chest or back

**Questions or comments?**

water, glycerin, propylene glycol, cocamidopropyl hydroxysultaine, sodium C14-16 olefin sulfonate, xanthan gum, citric acid, potassium hydroxide, methyl methacrylate/glycol dimethacrylate crosspolymer, sodium lauroyl lactylate, glycolic acid, ceramide NP, ceramide AP, phytosphingosine, cholesterol, carbomer, ceramide EOP

**Questions or comments?**

**1-888-768-2913**

**Drug Facts****Active ingredient**

Benzoyl peroxide 10%

**Purpose**

Acne treatment

**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**

- 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.

### **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 right away.

### ***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
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

### ***Inactive ingredients***

water, butylene glycol, C12-15 alkyl benzoate, glycerin, glyceryl stearate, PEG-100 stearate, cetearyl alcohol, phenoxyethanol, hydroxypropyl starch phosphate, polysorbate 60, dimethicone, xanthan gum, cetyl alcohol, bisabolol, tetrasodium EDTA, ethylhexylglycerin, methylisothiazolinone, benzalkonium chloride, sea whip extract, zingiber officinale (ginger) root extract, chamomilla recutita (matricaria) flower extract, alcohol, leuconostoc/radish root ferment filtrate, methylparaben, disodium EDTA, ethylparaben, methyl methacrylate/glycol dimethacrylate crosspolymer

### ***Questions or comments?***

**1-888-768-2913**

**KIT 80861-010-01**



**ACNE FREE®**  
DERMATOLOGY INSPIRED CARE

**2** TONE

**WITCH HAZEL  
MATTIFYING  
TONER**

SHINE CONTROL

**SEVERE ACNE**



WITCH HAZEL  
GLYCOLIC ACID  
ALOE VERA

**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.

**CAUTION:** Flammable until dry.

Keep away from flames and heat.

**Directions:** Use every morning and evening for toning. After cleansing apply to entire face with a cotton pad, avoiding the eye area. Do not rinse. May also be used on chest and/or back.

**Ingredients:** 2022003 1 Aqua / Water, Alcohol Denat., Hamamelis Virginiana Water / Witch Hazel Water, Hydrogenated Starch Hydrolysate, Glycerin, Polysorbate 20, Glycolic Acid, Sodium Hydroxide, Citric Acid, Bisabolol, Niacinamide, Aloe Barbadensis Leaf Juice Powder, Panthenol, Propylene Glycol, Disodium EDTA, Copper PCA, Lactic Acid, Chamomilla Recutita Flower Extract / Matricaria Flower Extract, Pantolactone. FIL code D220565/1

**Questions or Comments?** 1-888-768-2913

AcneFree is a brand committed to deliver quality products for oily and acne prone skin. It does not guarantee that you will be free of acne. This product was formulated to improve skin's appearance, but it is not a medicated acne product.

ACNEFREE.COM

AcneFree LLC, New York, NY 10001

Made in U.S.A. of U.S. and/or Imported Ingredients.

4 FL. OZ. (118ml)

5000000001984

**Warnings:** Avoid direct contact with eyes and lips. If contact occurs, rinse thoroughly with water. Always apply a broad-spectrum sunscreen while using retinol products and for 1 week after stopping use.

**Directions:** If you have never used retinol products, begin use two evenings a week, then gradually increase frequency to every other night, and finally once an evening as tolerated. Do not use in association with other products containing retinol.

**Ingredients:** Water, Mineral Oil, Cetearyl Alcohol, Glycerin, Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Polysorbate 60, Caprylic/Capric Triglyceride, Cetyl Alcohol, Bisabolol, Retinol, Sodium Hyaluronate, Xanthan Gum, Polysorbate 20, Allantoin, C12-15 Alkyl Benzoate, Cetyl Palmitate, Farnesol, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Ceramide 3, Cetyl Triethylmonium Dimethicone PEG-8 Succinate, Glycine Soja (Soybean) Sterols, Tridecyl Trimellitate, Triethanolamine, Disodium EDTA, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Methylisothiazolinone

**Questions or comments?** 1-888-768-2913

AcneFree is a brand committed to deliver quality products for oily and acne prone skin. It does not guarantee that you will be free of acne.

ACNEFREE.COM, AcneFree LLC, New York, NY 10001

Made in U.S.A. of U.S. and/or Imported Ingredients.

1 FL. OZ. (30ml)

5000000001981

**ACNE FREE®**  
DERMATOLOGY INSPIRED CARE

**3** EXFOLIATE   
PM

**RETINOL  
NIGHT CREAM**

HELPS SMOOTH SKIN

**SEVERE ACNE**



RETINOL COMPLEX  
CERAMIDE

**Warnings:** Avoid direct contact with eyes and lips. If contact occurs, rinse thoroughly with water. Always apply a broad-spectrum sunscreen while using retinol products and for 1 week after stopping use.

**Directions:** If you have never used retinol products, begin use two evenings a week, then gradually increase frequency to every other night, and finally once an evening as tolerated. Do not use in association with other products containing retinol.

**Ingredients:** Water, Mineral Oil, Cetearyl Alcohol, Glycerin, Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Polysorbate 60, Caprylic/Capric Triglyceride, Cetyl Alcohol, Bisabolol, Retinol, Sodium Hyaluronate, Xanthan Gum, Polysorbate 20, Allantoin, C12-15 Alkyl Benzoate, Cetyl Palmitate, Farnesol, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Ceramide 3, Cetyl Triethylmonium Dimethicone PEG-8 Succinate, Glycine Soja (Soybean) Sterols, Tridecyl Trimellitate, Triethanolamine, Disodium EDTA, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Methylisothiazolinone

**Questions or comments?** 1-888-768-2913

AcneFree is a brand committed to deliver quality products for oily and acne prone skin. It does not guarantee that you will be free of acne.

ACNEFREE.COM, AcneFree LLC, New York, NY 10001

Made in U.S.A. of U.S. and/or Imported Ingredients.

1 FL. OZ. (30ml)

5000000001981

**ACNE FREE®**  
DERMATOLOGY INSPIRED CARE

**3** EXFOLIATE   
PM

**RETINOL  
NIGHT CREAM**

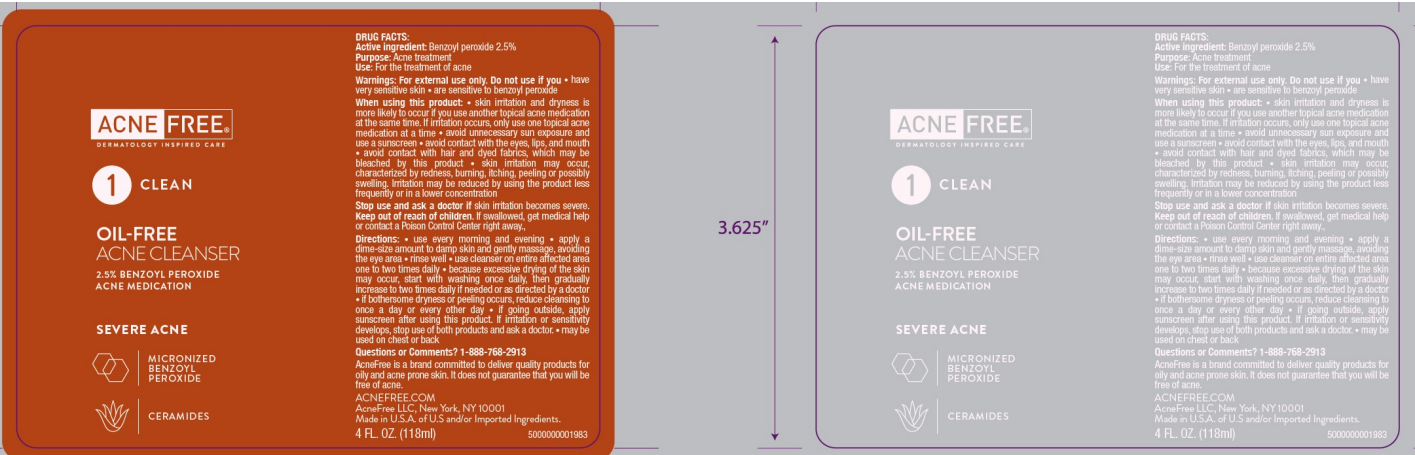
HELPS SMOOTH SKIN

**SEVERE ACNE**

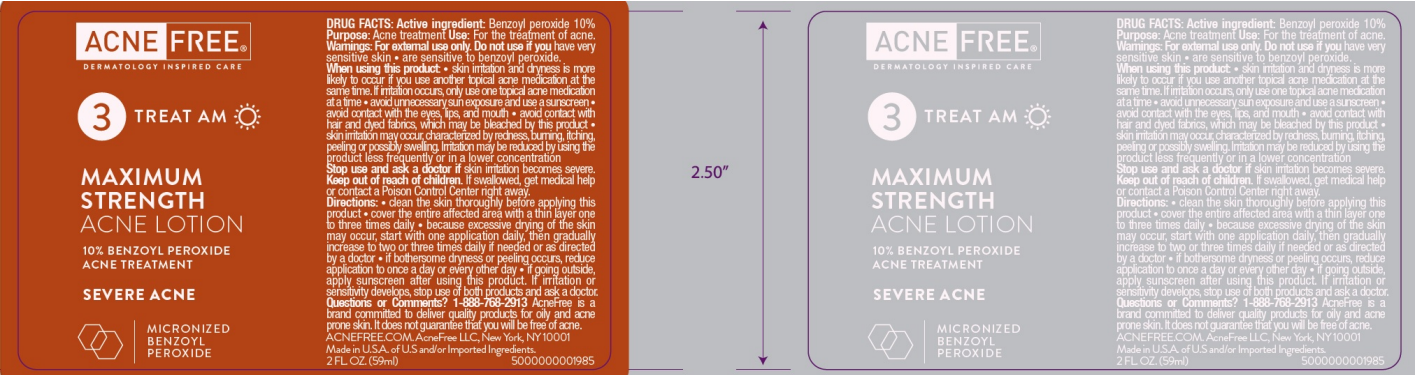


RETINOL COMPLEX  
CERAMIDE

**80861-004-01**



80861-011-01



# ACNE FREE SEVERE ACNE 24 HR ACNE CLEARING SYSTEM

benzoyl peroxide kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80861-010

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-010-01	1 in 1 KIT	12/01/2017	

Quantity of Parts			
Part #	Package Quantity		Total Product Quantity
Part 1	1 BOTTLE		118 mL
Part 2	1 BOTTLE		59 mL

## Part 1 of 2

## OIL FREE ACNE CLEANSER

benzoyl peroxide gel

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
METHYL METHACRYLATE (UNII: 196OC77688)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
CERAMIDE NP (UNII: 4370DF050B)	
CERAMIDE AP (UNII: F1X8L2B00J)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CERAMIDE 1 (UNII: 5THT33P7X7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-004-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	12/01/2017	



Part 2 of 2

MAXIMUM STRENGTH ACNE

benzoyl peroxide lotion

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL ALCOHOL (UNII: 936JT6JCN)	
LEVOMENOL (UNII: 24WE03BX2T)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
GINGER (UNII: C5529G5JPQ)	
CHAMOMILE (UNII: FGL3685T2X)	
ALCOHOL (UNII: 3K9958V90M)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	

Packaging

		Marketing Start	Marketing End
--	--	-----------------	---------------



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-011-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M006	12/01/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M006	12/01/2017	

**Labeler** - AcneFree, LLC (122237140)