

**ACNE FREE SENSITIVE SKIN 24 HR ACNE CLEARING SYSTEM- salicylic acid,
benzoyl peroxide
AcneFree LLC**

Acne Free SENSITIVE SKIN 24 HR Acne Clearing System KIT

Drug Facts

Active ingredient

Salicylic acid 1.5%

Purpose

Acne treatment

Use

for the treatment of acne

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.

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
- if bothersome dryness or peeling occurs, reduce application use
- may be used on chest or back

Other information

store at 60°–95° F (15°–35° C)

Inactive ingredients

water, sodium cocoyl isethionate, stearic acid, cocamidopropyl betaine, sodium lauroamphoacetate, disodium laureth sulfosuccinate, glycol distearate, polyacrylate-1 crosspolymer, benzyl alcohol, avena sativa (oat) kernel extract, sodium phytate, zinc PCA, glycerin, sorbic acid, ethyl vanillin, butylene glycol, sea whip extract, aminomethyl propanol

Questions or comments?

1-888-768-2913

Drug Facts

Active ingredient

Benzoyl peroxide 3%

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.

Other information

store at 60°–95° F (15°–35° C)

Inactive ingredients

water, ethyl macadamiate, propanediol, glycerin, butylene glycol, polyacrylamide, phenoxyethanol, C13-14 isoparaffin, bisabolol, laureth-7, allantoin, melaleuca alternifolia (tea tree) leaf oil, methylisothiazolinone, sodium hyaluronate, methyl methacrylate/glycol dimethacrylate crosspolymer, sodium hydroxide

Questions or comments?

1-888-768-2913

KIT 80861-007-01

DRUG FACTS:**Active ingredient:** Salicylic acid 1.5%**Purpose:** Acne treatment**Use:** For the treatment of acne**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.

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
- if bothersome dryness or peeling occurs, reduce application use
- may be used on chest or back

Other information: Store at 60°–95° F (15°–35° C)**Questions or Comments?** 1-888-768-2913

ACNE FREE[®]
DERMATOLOGY INSPIRED CARE

1 CLEAN

SALICYLIC ACID
ACNE CLEANSER

1.5% SALICYLIC ACID
ACNE TREATMENT

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, Bethesda, MD 20817

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

4 FL. OZ. (118ml)

5000000002670

SENSITIVE SKIN

SALICYLIC ACID



OATS

ACNE FREE®
DERMATOLOGY INSPIRED CARE

2 TONE

**FRUIT ENZYME
TONER**

ALCOHOL-FREE
BALANCES SKIN

Directions: Use every morning and evening. 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: Water, Niacinamide, Camellia Sinensis Leaf Extract, Pyrus Malus (Apple) Fruit Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Medica Limonum (Lemon) Extract, Sea Whip Extract, Saccharum Officinarum (Sugar Cane) Extract, Zingiber Officinale (Ginger) Root Extract, Pentylene Glycol, Benzyl Alcohol, Isoceteth-20, Aminomethyl Propanol, Salicylic Acid, Disodium EDTA, Bisabolol, Benzalkonium Chloride, Glycerin, Sorbic Acid, Butylene Glycol

Questions or Comments? 1-888-768-2913

SENSITIVE SKIN



FRUIT ENZYMES
GINGER

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, Bethesda, MD 20817
Made in U.S.A. of U.S and/or
Imported Ingredients.

4 FL. OZ. (118ml)

5000000002674

80861-009-01



3 TREAT

SENSITIVE SKIN ACNE LOTION

3% BENZOYL PEROXIDE
ACNE TREATMENT

DRUG FACTS:

Active ingredient: Benzoyl peroxide 3% **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.

SENSITIVE SKIN



GINGER
TEA TREE

Other information:

Store at 60°–95° F (15°–35° C)

Questions or Comments? 1-888-768-2913

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ACNEFREE.COM

AcneFree LLC, Bethesda, MD 20817

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

2 FL. OZ. (59ml)

500000002672

ACNE FREE SENSITIVE SKIN 24 HR ACNE CLEARING SYSTEM

salicylic acid, benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80861-007
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-007-01	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**SALICYLIC ACID ACNE CLEANSER**

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	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
OAT (UNII: Z6J799EAJK)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBIC ACID (UNII: X045WJ989B)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-008-01	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

SENSITIVE SKIN ACNE

benzoyl peroxide lotion

Product Information

Item Code (Source) NDC:80861-009

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	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LEVOMENOL (UNII: 24WE03BX2T)	
LAURETH-7 (UNII: Z95S6G8201)	
ALLANTOIN (UNII: 344S277G0Z)	
TEA TREE OIL (UNII: VIF565UC2G)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GINGER (UNII: C5529G5JPQ)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80861-009-01	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)