

**SKIN PHARMACY ADVANCED ACNE THERAPY KIT- salicylic acid, benzoyl peroxide
AMCOL Health & Beauty Solutions, Inc. DBA**

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.

Drug Facts

Active Ingredient

2% Salicylic Acid

Purpose

Acne Treatment

Use

- for the management of acne

Warnings

For external use only

Do not use this medication if you

- Have very sensitive skin
- Are sensitive to salicylic acid

Ask a doctor or pharmacist before use if you are

Using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product

- Skin irritation and dryness are 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.
- When using this product avoid contact with eyes. If this occurs, immediately flush with water.

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

Directions

- Use morning and night.
- Apply a dime sized amount to damp skin and gently massage for 1 to 2 minutes.
- Rinse thoroughly with warm water.
- Pat dry.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- **If going outside use sunscreen.**

Inactive ingredients

Water, Sodium C14-16 Olefin Sulfonate, Peg-8, Cocamidopropyl Betaine, Xanthan Gum, Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer, DMDM Hydantoin, Disodium EDTA, Tocopheryl Acetate, Hamamelis Virginiana (Witch Hazel) Water, Butylene Glycol, Sodium Benzotriazolyl Butylphenol Sulfonate, Calendula Officinalis Flower Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Phenoxyethanol, Yellow 5, Red 40, Fragrance.

M050775

Principal Display Panel - Skin+Pharmacy Advanced Acne Therapy Kit Carton Label

SKIN+PHARMACY

ADVANCED

ACNE THERAPY KIT

DERMATOLOGIST TESTED

BONUS:

Includes 2 Gentle Facial

Cleansing Sponges

exclusively at

CVS/pharmacy

\$35 VALUE

\$19.99

ONE MONTH SUPPLY

4 FL OZ (118 mL)

SKIN+PHARMACY

ADVANCED
**ACNE
THERAPY**

**CLARIFYING
DAILY CLEANSER**
with Polytrap® Technology

Maximum Strength
2% Salicylic Acid

- ◆ removes excess skin oils
- ◆ unclogs pores
- ◆ oil-free formula

exclusively at
CVS/pharmacy

4 FL OZ (118 mL)

**DERMATOLOGIST
TESTED**

Skin+Pharmacy Advanced Acne Therapy is an innovative line of clinically tested skin care products that help reduce the appearance of acne. These products, exclusive to CVS/pharmacy, are less irritating to skin, yet powerful enough to treat breakouts, kill acne-causing bacteria, and unclog pores. Let Skin+Pharmacy help improve your appearance toward a clear, acne-free complexion.

| | |
|--|----------------|
| Drug Facts | |
| Active ingredient | Purpose |
| 2% Salicylic Acid | Acne Treatment |
| Use ■ for the management of acne | |
| Warnings | |
| Do not use this medication if you | |
| ■ Have very sensitive skin ■ Are sensitive to salicylic acid | |
| Ask a doctor or pharmacist before use if you are | |
| Using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. | |
| When using this product | |
| ■ Skin irritation and dryness are 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. ■ When using this product avoid contact with eyes. If this occurs, immediately flush with water. | |
| Keep out of reach of children. In case of accidental ingestion, get medical help or contact Poison Control Center right away | |
| Directions | |
| ■ Use morning and night. ■ Apply a dime sized amount to damp skin and gently massage for 1 to 2 minutes. ■ Rinse thoroughly with warm water. Pat dry. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ■ If going outside use sunscreen. | |
| Inactive ingredients | |
| Water, Sodium C14-16 Olefin Sulfonate, PEG-8, Cocamidopropyl Betaine, Xanthan Gum, Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer, DMDM Hydantoin, Disodium EDTA, Tocopheryl Acetate, Hamamelis Virginiana (Witch Hazel) Water, Butylene Glycol, Sodium Benzotriazolyl Butylphenol Sulfonate, Calendula Officinalis Flower Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Phenoxyethanol, Yellow 5, Red 40, Fragrance. | |

Principal Display Panel - Skin+Pharmacy Advanced Acne Therapy Kit Label

SKIN+PHARMACY

ADVANCED
**ACNE
THERAPY**

ACTIVE CLEARING LOTION
with Microsponge® Technology

2.5% Benzoyl Peroxide

- clinically proven to kill acne-causing bacteria
- clinically proven to effectively reduce inflammatory lesions
- soothing, oil-free formula
- unclogs pores
- fragrance free

DERMATOLOGIST TESTED

exclusively at
CVS/pharmacy

0.75 FL OZ (22 mL)

Side Seam - Overlap

Side Seam - Overlap

Side Seam - Overlap

SKIN+PHARMACY

ADVANCED ACNE THERAPY

ACTIVE CLEARING LOTION
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- ◆ clinically proven to kill acne-causing bacteria
- ◆ clinically proven to effectively reduce inflammatory lesions
- ◆ soothing, oil-free formula
- ◆ unclogs pores
- ◆ fragrance free



exclusively at
CVS/pharmacy

0.75 FL OZ (22 mL)

Active Ingredient Benzoyl Peroxide 2.5% for acne treatment. **Warning: 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 after using this product. Avoid contact with lips, eyes, or mouth. If product gets into the eyes rinse thoroughly with water. Skin irritation may occur, characterized by redness, burning, itching, peeling, or possible swelling. Irritation may be reduced by using the product less frequently or in lower concentration. Avoid contact with hair and dyed fabrics, which may be bleached by this product. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. **Stop use and ask a doctor** if irritation becomes severe. **Keep out of reach of children.** Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away. **Directions:** Clean skin thoroughly before applying this product. Apply a thin layer to affected area one to two times per day. 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. **See carton for complete labeling** MO50776

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 Microsponge® is a © 2014 CVS/pharmacy CVS.com® 1-800-SHOP CVS **CVS Quality** registered trademark of Money Back Guarantee AMCOL International Corp. Made in the U.S.A. of U.S. and imported components V-13649

Side Seam - Overlap

Side Seam - Overlap

Side Seam - Overlap

Principal Display Panel - Skin+Pharmacy Advanced Acne Therapy Kit Label

SKIN+PHARMACY

ADVANCED

**ACNE
THERAPY**

**SPOT TREATMENT
with Microsponge® Technology**

5% Benzoyl Peroxide

- clinically proven to effectively reduce inflammatory lesions
- effectively kills acne-causing bacteria
- helps reduce irritation
- fragrance free

DERMATOLOGIST TESTED

exclusively at
CVS/pharmacy

0.4 FL OZ (12 mL)

Side Seam – Overlap

Side Seam – Overlap

SKIN+PHARMACY

ADVANCED ACNE THERAPY

SPOT TREATMENT
with Microsponge® Technology

5% Benzoyl Peroxide

- ◆ clinically proven to effectively reduce inflammatory lesions
- ◆ effectively kills acne-causing bacteria
- ◆ helps reduce irritation
- ◆ fragrance free

exclusively at
CVS/pharmacy



0.4 FL OZ (12 mL)

Active Ingredient Benzoyl Peroxide 5% for acne treatment. **Warning:** 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 lips, eyes, or mouth. If product gets into the eyes, rinse thoroughly with water. 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 lower concentration. Avoid contact with hair and oiled fabrics, which may be bleached by this product. **Stop use and ask a doctor if** irritation becomes severe. **Keep out of reach of children.** Do not swallow. 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. If going outside apply sunscreen after using this product. Keep tightly closed. Avoid storing at extreme temperatures (below 40° F and above 100° F). See carton for complete labeling.

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Made in the U.S.A. of U.S. and imported components V-13649

Side Seam – Overlap

Side Seam – Overlap

SKIN PHARMACY ADVANCED ACNE THERAPY KIT

salicylic acid, benzoyl peroxide kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68634-067 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68634-067-01 | 1 in 1 CARTON; Type 0: Not a Combination Product | 10/01/2014 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 TUBE | 118 mL |
| Part 2 | 1 TUBE | 22 mL |
| Part 3 | 1 TUBE | 12 mL |

Part 1 of 3**SKIN PHARMACY ADVANCED ACNE THERAPY CLARIFYING DAILY CLEANSER**

salicylic acid liquid

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 | 20 g in 2 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0K00R) | |
| sodium C14-16 olefin sulfonate (UNII: O9W3D3YF5U) | |
| polyethylene glycol 4000 (UNII: 4R4HF16D95) | |
| cocamidopropyl betaine (UNII: 5OCF3O11KX) | |
| Xanthan gum (UNII: TTV12P4NEE) | |
| DMDM Hydantoin (UNII: BYR0546TOW) | |
| edetate disodium (UNII: 7FLD91C86K) | |
| .alpha.-tocopherol acetate, DL- (UNII: WR1WPI7EW8) | |
| Hamamelis virginiana flower water (UNII: 222MYC9QUV) | |
| Butylene glycol (UNII: 3XUS85K0RA) | |
| Calendula Officinalis flower (UNII: P0M7O4Y7YD) | |
| licorice (UNII: 61ZBX54883) | |
| Phenoxyethanol (UNII: HIE492ZZ3T) | |

FD&C Yellow No. 5 (UNII: I753WB2F1M)

FD&C red no. 40 (UNII: WZB9127XOA)

Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer (UNII: EX0F4CZ66H)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 118 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 | 10/01/2014 | |

Part 2 of 3

SKIN PHARMACY ADVANCED ACNE THERAPY ACTIVE CLEARING

benzoyl peroxide lotion

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 g in 2 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| glycerin (UNII: PDC6A3C0OX) | |
| methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q) | |
| cetyl alcohol (UNII: 936JST6JCN) | |
| sorbitol (UNII: 506T60A25R) | |
| glyceryl dilaurate (UNII: MFL3ZIE8SK) | |
| stearyl alcohol (UNII: 2KR89I4H1Y) | |
| magnesium aluminum silicate (UNII: 6M3P64V0NC) | |
| sodium citrate (UNII: 1Q73Q2JULR) | |
| silicon dioxide (UNII: ETJ7Z6XBU4) | |
| sodium lauryl sulfate (UNII: 368GB5141J) | |
| citric acid monohydrate (UNII: 2968PHW8QP) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| xanthan gum (UNII: TTV12P4NEE) | |
| propylparaben (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 22 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 | 10/01/2014 | |

Part 3 of 3

SKIN PHARMACY ADVANCED ACNE THERAPY SPOT TREATMENT

benzoyl peroxide lotion

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 | 50 g in 2 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| glycerin (UNII: PDC6A3C0OX) | |
| methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q) | |
| cetyl alcohol (UNII: 936JST6JCN) | |
| sorbitol (UNII: 506T60A25R) | |
| glyceryl dilaurate (UNII: MFL3ZIE8SK) | |
| stearyl alcohol (UNII: 2KR89I4H1Y) | |
| magnesium aluminum silicate (UNII: 6M3P64V0NC) | |
| sodium citrate (UNII: 1Q73Q2JULR) | |
| silicon dioxide (UNII: ETJ7Z6XBU4) | |
| sodium lauryl sulfate (UNII: 368GB5141J) | |
| citric acid monohydrate (UNII: 2968PHW8QP) | |
| methylparaben (UNII: A2I8C7HI9T) | |
| xanthan gum (UNII: TTV12P4NEE) | |
| propylparaben (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 12 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 | 10/01/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 10/01/2014 | |

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|---|
| AMCOL Household & Personal Care | | 872684803 | MANUFACTURE(68634-067) , PACK(68634-067) , LABEL(68634-067) , ANALYSIS(68634-067) |

Revised: 10/2016

AMCOL Health & Beauty Solutions, Inc. DBA