

**KLEER-PLEX ADVANCED ACNE CARE SYSTEM- salicylic acid**  
**Bio-Medical & Pharmaceutical Manufacturing Corporation**

*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.*

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**Kleer-Plex Advanced Acne Care System**

**THIS SYSTEM CONTAINS:**

(1) Foaming Acne Clarifier

NDC 37945-870-40

(1) Pore Purifier & Toner

(1) Penetrating Acne Gel

NDC 37945-874-11

(1) Targeted Acne Pen

NDC 37945-894-05

**DRUG FACTS**

Acne Treatment Wash and Acne Treatment Gel

**Active Ingredient**

Salicylic Acid, 2%

**Purpose**

Acne Treatment

**Uses**

- For the management of acne.
- Clears up most acne pimples, blackheads, and whiteheads and allows skin to heal.
- Penetrates pores to eliminate most acne blemishes.
- Helps prevent new acne pimples.

**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**

## **Directions**

### Acne Treatment Wash

- At least once each day, dispense a small amount of cleanser onto an exfoliating pad or cloth.
- Add a small amount of water and work into a lather on the face using small circular motions avoiding the eyes.
- Repeat after perspiration or makeup use.
- If dryness occurs, reduce frequency to once each day.

### Acne Treatment Gel

- Each night, dispense a small amount of gel onto the fingertips.
- Spread gel sparingly on the face and other affected areas using small circular motions avoiding the eyes.
- Repeat after perspiration or makeup use.
- If dryness occurs, reduce frequency to once each day.

### **Sensitivity Test for a New User - Acne Treatment Gel**

- Apply product sparingly to one or two small affected areas during the first 3 days.
- If no discomfort occurs, follow the directions stated above.

## **Inactive Ingredients**

### Acne Treatment Wash

Purified Water, Ammonium Lauryl Sulfate, Lauramidopropyl Betaine, Propylene Glycol, Hydroxypropyl Bis-Hydroxyethylidimonium Chloride, Triethanolamine, Hydroxypropylmethylcellulose, Magnesium Sulfate, 3-iodo-2-propynylbutylcarbamate, Diazolidinyl Urea, Peppermint Oil, Methylparaben, Propylparaben.

### Acne Treatment Gel

Purified Water, Alcohol, Glycerin, Xanthan Gum, Polysorbate 20, Peppermint Oil, (.Alpha.-Tocopherol Acetate), Wheat Germ Oil, Glycolic Acid, Tert-Butyl Alcohol, Brucine Sulfate.

## **Questions or Comments**

281-835-8051

M-F 8 AM to 5 PM

## **Kleer-Plex Advanced Acne System**

### **Principal Display Panel**

**NDC# 37945-876-91**

KleerPlexFront.jpg

**Kleer-Plex**<sup>®</sup>  
Kleer-Plex

**ADVANCED • ACNE • CARE • SYSTEM**

- Icon 1: Blue snowflake-like molecule structure
- Icon 2: Green cluster of molecules
- Icon 3: Yellow cluster of molecules
- Icon 4: Red leaf-like structure

**WWW.KLEER-PLEX.COM**





NDC 37945-876-91

KleerPlexBack.jpg



ADVANCED • ACNE • CARE • SYSTEM

**THIS SYSTEM CONTAINS:**

-  (1) Foaming Acne Clarifier  
NDC 37945-870-40
-  (1) Pore Purifier & Toner
-  (1) Penetrating Acne Gel  
NDC 37945-874-11
-  (1) Targeted Acne Pen  
NDC 37945-894-05

<b>DRUG FACTS</b>	
Acne Treatment Wash	
Active Ingredient	Purpose
Salicylic Acid, 2%.....	Acne Treatment
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• For the management of acne.</li> <li>• Clears up most acne pimples, blackheads, and whiteheads and allows skin to heal.</li> <li>• Penetrates pores to eliminate most acne blemishes.</li> <li>• Helps prevent new acne pimples.</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>• For external use only.</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time.</li> <li>• If irritation occurs, only use one topical acne medication at a time.</li> </ul>	
<b>KEEP OUT OF REACH OF CHILDREN</b>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• At least once each day, dispense a small amount of cleanser onto an exfoliating pad or cloth.</li> <li>• Add a small amount of water and work into a lather on the face using small circular motions avoiding the eyes.</li> <li>• Repeat after perspiration or makeup use.</li> <li>• If dryness occurs, reduce frequency to once each day.</li> </ul>	
<b>Inactive Ingredients</b>	
Purified Water, Ammonium Lauryl Sulfate, Lauramidopropyl Betaine, Propylene Glycol, Hydroxypropyl Bis-Hydroxyethylmonium Chloride, Triethanolamine, Hydroxypropylmethylcellulose, Magnesium Sulfate, 3-iodo-2-propenylbutylcarbamate, Diazolidinyl Urea, Peppermint Oil, Methylparaben, Propylparaben.	
<b>Questions or Comments</b>	
281-835-8051 M-F 8 AM to 5 PM	

<b>DRUG FACTS</b>	
Acne Treatment Gel	
Active Ingredient	Purpose
Salicylic Acid, 2%.....	Acne Treatment
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• For the management of acne.</li> <li>• Clears up most acne pimples, blackheads, and whiteheads and allows skin to heal.</li> <li>• Penetrates pores to eliminate most acne blemishes.</li> <li>• Helps prevent new acne pimples.</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>• For external use only.</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time.</li> <li>• If irritation occurs, only use one topical acne medication at a time.</li> </ul>	
<b>KEEP OUT OF REACH OF CHILDREN</b>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Each night, dispense a small amount of gel onto the fingertips.</li> <li>• Spread gel sparingly on the face and other affected areas using small circular motions avoiding the eyes.</li> <li>• Repeat after perspiration or makeup use.</li> <li>• If dryness occurs, reduce frequency to once each day.</li> </ul>	
<b>Sensitivity Test for a New User</b>	
<ul style="list-style-type: none"> <li>• Apply product sparingly to one or two small affected areas during the first 3 days.</li> <li>• If no discomfort occurs, follow the directions stated above.</li> </ul>	
<b>Inactive Ingredients</b>	
Purified Water, Alcohol, Glycerin, Xanthan Gum, Polysorbate 20, Peppermint Oil, (Alpha.-Tocopherol Acetate), Wheat Germ Oil, Glycolic Acid, Tert-Butyl Alcohol, Brucine Sulfate.	
<b>Questions or Comments</b>	
281-835-8051 M-F 8 am to 5 pm	

**Kleer-Plex™ Pore Purifier & Toner**

Extract of Witchhazel, Horse Chestnut, White Oak Bark, Echinacea, Chaste Tree Berry, and Goldenseal, (Cert. Org. GMO-Free Ethanol and Cert. Org Lavender Oil), Polysorbate 20, (Ethyl Lauroyl Arginate HCl and Glycerin), Distilled Lemon Oil, Phenyl Ethyl Alcohol, (Butylene Glycol and 10-Hydroxydecanoic Acid and Sebacic Acid and 1, 10-Decanediol).

[WWW.KLEER-PLEX.COM](http://WWW.KLEER-PLEX.COM)

MANUFACTURED BY BIO-MEDICAL & PHARM. MFG. CORP. | 4311 SOUTH DR., HOUSTON, TX 77053

**KLEER-PLEX ADVANCED ACNE CARE SYSTEM**

salicylic acid kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37945-876
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-876-91	1 in 1 KIT; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PUMP	118 mL
Part 2	1 BOTTLE	236.558 mL
Part 3	1 BOTTLE	30 mL
Part 4	1 APPLICATOR	15 mL

**Part 1 of 4****KLEER-PLEX FOAMING ACNE CLARIFIER**

salicylic acid liquid

**Product Information**

Item Code (Source)	NDC:37945-870
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 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYPROPYL BIS-HYDROXYETHYLDIMONIUM CHLORIDE (UNII: 1EO3O1X7HG)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-870-40	1 in 1 BOX		
1		118 mL in 1 BOTTLE, PUMP; 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	11/03/2014	

## Part 2 of 4

### KLEER-PLEX PORE PURIFIER AND TONER

face and neck (excluding shaving preparations)

## Product Information

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WITCH HAZEL (UNII: 101I4J0U34)	
INGR	HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
INGR	WHITE OAK BARK (UNII: 93LP7Y8EGT)	
INGR	ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
INGR	CHASTE TREE (UNII: 433OSF3U8A)	
INGR	GOLDENSEAL (UNII: ZW3Z11D0JV)	
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	ETHYL LAUROYL ARGINATE HYDROCHLORIDE (UNII: XPD6ZY79TB)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	LEMON OIL, DISTILLED (UNII: ET5GD00TRP)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	10-HYDROXYDECANOIC ACID (UNII: NP03XO416B)	
INGR	SEBACIC ACID (UNII: 97AN39ICTC)	
INGR	1,10-DECANEDIOL (UNII: 5I577UDK52)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236.558 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

## Part 3 of 4

### KLEER-PLEX PENETRATING ACNE

salicylic acid gel

## Product Information

Item Code (Source)	NDC:37945-874
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 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHEAT GERM OIL (UNII: 14C97E680P)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
BRUCINE SULFATE (UNII: KY7O12XPOQ)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-874-11	1 in 1 BOX		
1		30 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 final	part333D	10/22/2014	

## Part 4 of 4

### KLEER-PLEX TARGETED ACNE PEN

salicylic acid gel

#### Product Information

Item Code (Source)	NDC:37945-894
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 mg in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHEAT GERM OIL (UNII: 14C97E680P)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
BRUCINE SULFATE (UNII: KY7012XPOQ)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-894-05	1 in 1 BOX		
1		15 mL in 1 APPLICATOR; 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	10/22/2014	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	11/03/2014	

**Labeler** - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

## Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-876, 37945-870, 37945-874, 37945-894)

Revised: 11/2014

Bio-Medical & Pharmaceutical Manufacturing Corporation