

## **30 DAY ACNE TREATMENT KIT- salicylic acid, benzoyl peroxide**

### **Cosmetic Enterprises Ltd**

*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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## **30 day Acne Treatment Kit**

### **Acne Cleanser**

Active ingredients Purpose

Salicylic Acid 0.5% Acne Medication

### **Acne Lotion**

Active Ingredient Purpose

Benzoyl Peroxide 5% Acne treatment

**Use** - For the Treatment of acne

**Keep this and all drugs out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Stop use and ask a doctor** if irritation becomes severe.

### **Acne Cleanser**

#### **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 medication at a time.
- Avoid contact with eyes, If contact occurs, flush thoroughly with water.

### **Acne Lotion**

#### **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 medication at a

time

- Avoid unnecessary sun exposure and use a sunscreen
- Avoid contact with 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 lower concentration.

## **Acne Cleanser**

### ***Directions:***

- Cleanse twice a day.
- Wet face. Apply to hands, add water and work into lather.
- Massage Face gently.
- Rinse thoroughly.

## **Acne Lotion**

### ***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 directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day
- If going outside, apply a sunscreen after using this product
- If irritation or sensitivity develops, stop use of both products and ask a doctor

## **Acne Cleanser**

### ***Inactive ingredients:***

Water, Decyl Polyglucose, Laurel Glucoside, Cocamidopropyl Betaine, Glycerin, Xanthan Gum, Sodium Cocoyl Hydrolyzed Amaranth Protein, Malaleuca Alternifolia (Australian Tea Tree) Leaf Extract, Polysorbate 20, Backhousia Citriodora (Australian Myrtle) Leaf Extract, Fusanus Spicatus (Australian Sandalwood) Extract, Disodium EDTA.

## **Acne Lotion**

### ***Inactive Ingredients:***

Water, Dimethicone, Cetyl Alcohol, Propylene Glycol, Polyacrylate 13/polyisobutene/ Polysorbate 20, Cocamidopropyl Betaine, Glycerin, Backhouseia Citriodora (Australian Myrtle) Leaf Extract, Fusanus Spicatus (Australian Sandalwood) Extract, Aloe Barbadensis Leaf Juice, Sodium Benzoate, Pentylene Glycol, C12-15 Alkyl Benzoate, Phenoxyethanol.

Organiclear Acne Kit

## ORGANICLEAR ACNE CLEANSER

<b>Drug Facts</b>	
<b>Active ingredient</b> Salicylic Acid 0.5%	<b>Purpose</b> Acne Medication
<b>Use</b> - For the treatment of acne	
<b>Warnings:</b> For external use only <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. If irritation occurs, only use one topical medication at a time.</li> <li>• Avoid contact with eyes. If contact occurs, flush thoroughly with water.</li> </ul> <ul style="list-style-type: none"> <li>• <b>KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</li> </ul>	
<b>Directions:</b> <ul style="list-style-type: none"> <li>• Cleanse twice a day.</li> <li>• Wet face. Apply to hands, add water and work into lather.</li> <li>• Massage face gently.</li> <li>• Rinse thoroughly.</li> </ul>	
<b>Inactive ingredients:</b> Water, Decyl Polyglucose, Laurel Glucoside, Cocamidopropyl Betaine, Glycerin, Xanthan Gum, Sodium Cocoyl Hydrolyzed Amaranth Protein, Malaeuca Altemifolia (Australian Tea Tree) Leaf Extract, Polysorbate 20, Backhousia Citriodora (Australian Myrtle) Leaf Extract, Fusanus Spicatus (Australian Sandalwood) Extract, Disodium EDTA.	

## ORGANICLEAR SOOTHING LOTION

<b>Directions:</b> <ul style="list-style-type: none"> <li>• Cleanse the skin thoroughly before applying medication.</li> <li>• Cover the entire treatment area with a thin layer once daily at bedtime.</li> </ul>
<b>Ingredients:</b> Water, Dimethicone, Cetyl Alcohol, Polyacrylate 13/ Polyisobutene/Polysorbate 20, Glycerin, Melaleuca Altemifola (Australian Tea Tree) Leaf Extract, Backhousia Citriodora (Australian Myrtle) Leaf Extract, Chamomilla Recutita (Matricaria) Extract, Fusanus Spicatus (Australian Sandalwood) Extract, Pentylene Glycol, Sodium Benzoate, Lactic Acid and Phenoxyethanol.

## ORGANICLEAR ACNE LOTION

<b>Drug Facts</b>	
<b>Active ingredient</b> Benzoyl Peroxide 5%	<b>Purpose</b> Acne treatment
<b>Use</b> - For the treatment of acne	
<b>Warnings:</b> <ul style="list-style-type: none"> <li>• For external use only.</li> <li>• <b>Do not use</b> if you <ul style="list-style-type: none"> <li>• have very sensitive skin.</li> <li>• are sensitive to benzoyl peroxide.</li> </ul> </li> <li>• <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. If irritation occurs, only use one topical medication at a time.</li> <li>• Avoid unnecessary sun exposure and use a sunscreen.</li> <li>• Avoid contact with eyes, lips and mouth.</li> <li>• Avoid contact with hair and dyed fabrics, which may be bleached by this product.</li> <li>• 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.</li> </ul> </li> <li>• <b>Stop use and ask a doctor</b> if irritation becomes severe.</li> <li>• <b>KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</li> </ul>	
<b>Directions:</b> <ul style="list-style-type: none"> <li>• Clean the skin thoroughly before applying this product.</li> <li>• Cover the entire affected area with a thin layer one to three times daily.</li> <li>• 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 directed by a doctor.</li> <li>• If bothersome dryness or peeling occurs, reduce application to once a day or every other day.</li> <li>• If going outside, apply a sunscreen after using this product.</li> <li>• If irritation or sensitivity develops, stop use of both products and ask a doctor.</li> </ul>	
<b>Inactive ingredients:</b> Water, Dimethicone, Cetyl Alcohol, Propylene Glycol, Polyacrylate 13/Polyisobutene/Polysorbate 20, Cocamidopropyl Betaine, Glycerin, Backhousia Citriodora (Australian Myrtle) Leaf Extract, Fusanus Spicatus (Australian Sandalwood) Extract, Aloe Barbadosensis Leaf Juice, Sodium Benzoate, Pentylene Glycol, C12-15 Alkyl Benzoate, Phenoxyethanol.	

## 30 DAY ACNE TREATMENT KIT

salicylic acid, benzoyl peroxide kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56152-0250
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-0250-1	1 in 1 KIT; Type 0: Not a Combination Product	08/23/2023	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	90 mL
Part 2		1
Part 3	1 TUBE	180 mL

### Part 1 of 3

## ORGANICLEAR ACNE

benzoyl peroxide lotion

### Product Information

Item Code (Source)	NDC:56152-0251
Route of Administration	TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BACKHOUSIA CITRIODORA LEAF</b> (UNII: FKN73KG747)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>SANTALUM SPICATUM WHOLE</b> (UNII: O8PUT104O1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:56152-0251-1	90 mL in 1 TUBE; Type 0: Not a Combination Product	
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	08/23/2023	

## Part 2 of 3

### ORGANICLEAR SOOTHING LOTION

lotions, oils, powders, and creams lotion

## Product Information

Route of Administration	TOPICAL
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## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	BACKHOUSIA CITRIODORA LEAF (UNII: FKN73KG747)	
INGR	SANTALUM SPICATUM WHOLE (UNII: O8PUT104O1)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		08/24/2023	

## Part 3 of 3

### ORGANICLEAR ACNE CLEANSER

salicylic acid cream

## Product Information

Item Code (Source) NDC:56152-0252

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BACKHOUSIA CITRIODORA LEAF (UNII: FKN73KG747)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
SANTALUM SPICATUM WHOLE (UNII: O8PUT104O1)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-0252-1	180 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	M006	08/23/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	08/23/2023	

**Labeler** - Cosmetic Enterprises Ltd (017701475)