

**ACNE THERAPY BAR- sulfur soap**  
**PSODEX USA INC**

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**Anti Acne Soap Bar**

Acne is a common skin condition that can fluctuate over time.

The main goal of treatment is to manage symptoms.

PSODEX Acne Therapy Soap Bar offers a soothing formula that helps block the recurrence of acne symptoms with the help of SULFUR.

**PREVENTS:**

Excessive sebum secretion

**RELIEVES:**

Itching, inflammation, and roughness

**CONTROLS:**

Flaking and scaling

**HELPS BLOCK:**

Recurrence of acne symptoms

**Active Ingredient / Purpose**

Active ingredient: Sulfur 3%

Purpose: Acne treatment

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**Inactive Ingredients**

Aloe Barbadensis Extract,  
Allantoin, Benzalkonium Chloride, Camellia Sinensis Extract,  
Citric Acid, Colloidal Oatmeal, Distilled Water, Glycerin,  
Mentha Piperita Leaf Extract, Melaleuca Alternifolia Leaf Oil,  
Permethrin, Sodium Chloride, Sodium Citrate, Sodium  
Laurate, Sodium Stearate, Sorbitol, Tetrasodium Etidronate

**USE**

Use: For the treatment of acne

DISTRIBUTED BY: Psodex USA Inc.

9898 Bissonnet St Ste 625 Houston, TX 77036

1-844 4PSODEX [www.psodexusa.com](http://www.psodexusa.com)

MANUFACTURED FOR

Yesim Derma Laboratories

**Directions:**

Wet affected area with warm water. Foam the soap in hands and apply to the affected area. Massage gently into the skin for 10-20 seconds, then rinse thoroughly. Use up to 2 times per day or as directed by a doctor. Avoid excessive drying of the skin by limiting the

time of contact to 10 seconds or less each time

**Ask a doctor before use if:**

You are pregnant or breastfeeding.

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**Stop use and ask a doctor if:**

Condition worsens or does not improve after regular use of this product as directed.

**Questions or Comments:**

1 844 4PSODEX | [info@psodexusa.com](mailto:info@psodexusa.com)

**Keep out of reach of children:**

If swallowed, get medical help or contact a Poison Control Center right away.

**Do not use :**

On damaged or irritated skin not caused by acne or on the sensitive skin

**When using this product :**

Avoid contact with hair and dyed fabrics, which may be bleached by this product. Skin irritation may occur. Start with one application daily, then gradually increase to two times daily if needed, or as directed by a doctor

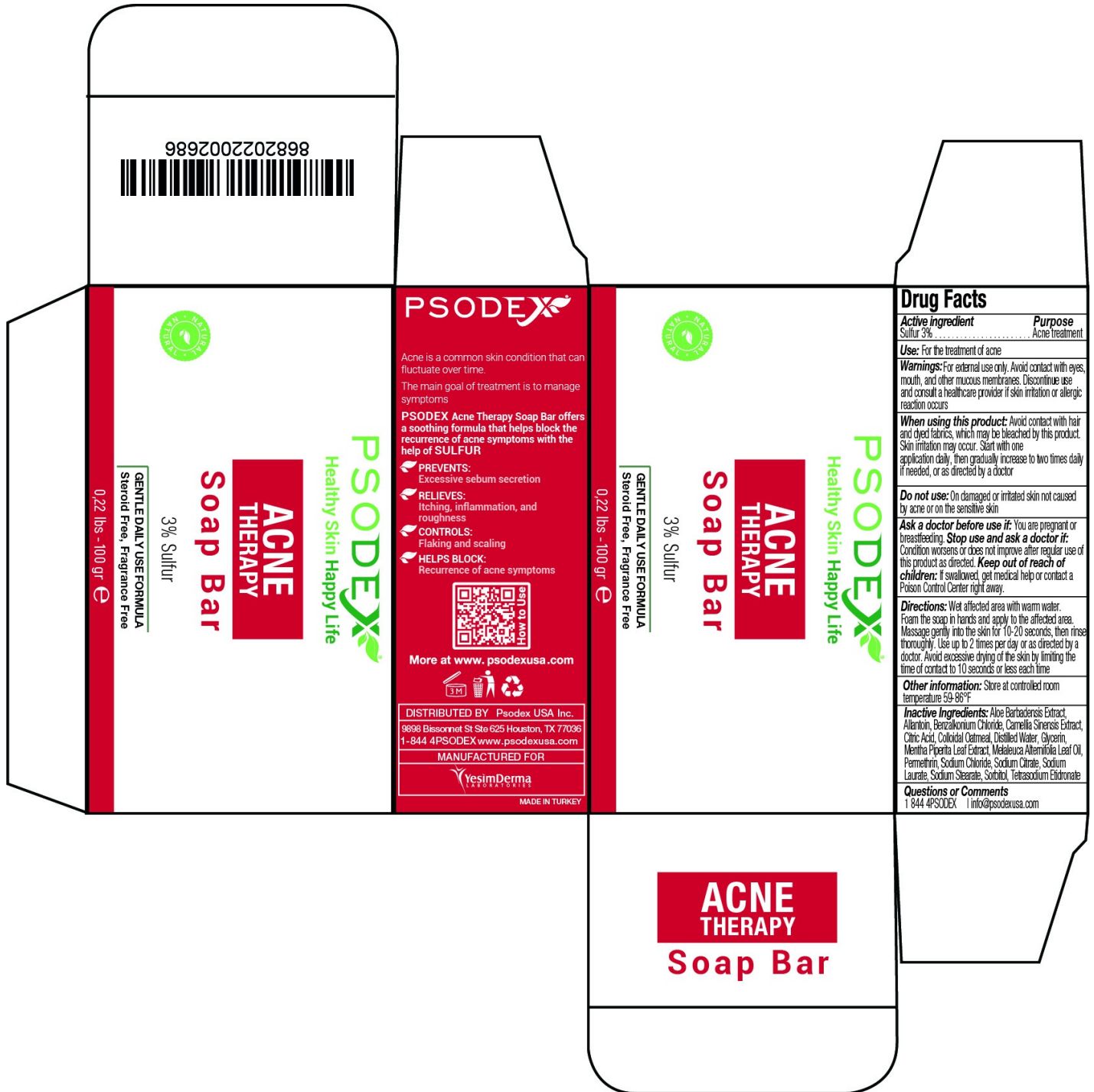
**Other information :**

Store at controlled room temperature 59-86°F

**Warnings:**

For external use only

**Acne Therapy Soap Bar**



**Drug Facts**

Active ingredient	Purpose
Sulfur 3%	Acne treatment

**Use:** For the treatment of acne

**Warnings:** For external use only. Avoid contact with eyes, mouth, and other mucous membranes. Discontinue use and consult a healthcare provider if skin irritation or allergic reaction occurs

**When using this product:** Avoid contact with hair and dyed fabrics, which may be bleached by this product. Skin irritation may occur. Start with one application daily, then gradually increase to two times daily if needed, or as directed by a doctor

**Do not use:** On damaged or irritated skin not caused by acne or on the sensitive skin

**Ask a doctor before use if:** You are pregnant or breastfeeding. **Stop use and ask a doctor if:** Condition worsens or does not improve after regular use of this product as directed. **Keep out of reach of children:** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions:** Wet affected area with warm water. Foam the soap in hands and apply to the affected area. Massage gently into the skin for 10-20 seconds, then rinse thoroughly. Use up to 2 times per day or as directed by a doctor. Avoid excessive drying of the skin by limiting the time of contact to 10 seconds or less each time

**Other information:** Store at controlled room temperature 59-86°F

**Inactive Ingredients:** Aloe Barbadensis Extract, Allantoin, Benzalkonium Chloride, Camellia Sinensis Extract, Citric Acid, Colloidal Catmeal, Distilled Water, Glycerin, Mentha Piperita Leaf Extract, Melaleuca Alternifolia Leaf Oil, Permethrin, Sodium Chloride, Sodium Citrate, Sodium Laurate, Sodium Stearate, Sorbitol, Tetrasodium Edidronate

**Questions or Comments**  
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**ACNE THERAPY BAR**  
sulfur soap

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73503-013
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	3 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SORBITOL</b> (UNII: 506T60A25R)	10 g in 100 g
<b>TEA LEAF OIL</b> (UNII: VC855RRT77)	5 g in 100 g
<b>PERMETHRIN</b> (UNII: 509F88P9SZ)	1 g in 100 g
<b>ETIDRONATE TETRASODIUM</b> (UNII: CZZ9T1T1X4)	0.25 g in 100 g
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	2 g in 100 g
<b>MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL</b> (UNII: VIF565UC2G)	1 g in 100 g
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	0.25 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	0.1 g in 100 g
<b>MENTHA PIPERITA LEAF</b> (UNII: A389O33LX6)	7 g in 100 g
<b>SODIUM LAURATE</b> (UNII: K146MR5EXO)	10 g in 100 g
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	7 g in 100 g
<b>OATMEAL</b> (UNII: 8PI54V663Y)	2 g in 100 g
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	0.25 g in 100 g
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	0.25 g in 100 g
<b>WATER</b> (UNII: 059QF0KO0R)	17 mL in 100 g
<b>SODIUM STEARATE</b> (UNII: QU7E2XA9TG)	10 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	23.9 g in 100 g

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73503-013-00	1000 g in 1 BOX; Type 0: Not a Combination Product	01/01/2024	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M006	01/01/2024	

**Labeler** - PSODEX USA INC (076051073)**Registrant** - PSODEX USA INC (076051073)

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## Establishment

Name	Address	ID/FEI	Business Operations
BERKO ILAC VE KIMYA SANAYI ANONIM SIRKETI-SULTANBEYLI SUBESI		533135007	manufacture(73503-013)

Revised: 12/2023

PSODEX USA INC