

## **ACTIV O2 ACNE TREATMENT CLEANSING BAR- salicylic acid soap**

**Activ Ozone (pty) 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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## **ACTIV O<sub>2</sub> ACNE TREATMENT CLEANSING BAR**

### ***Drug Facts***

#### ***Active ingredient***

Salicylic acid 2%

#### ***Purpose***

Acne treatment

#### ***Uses***

• for the management or treatment of acne. Clears up acne blemishes, acne pimples, blackheads, whiteheads, and allows skin to heal. • helps prevent the development of new acne pimples, blackheads and whiteheads.

#### ***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. • avoid contact with the eyes, lips and mouth. • skin irritation may occur such as redness, burning, itching and peeling.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Directions***

##### **USE ONE TO THREE TIMES DAILY**

• wet your face or affected body parts with luke warm water, lather soap in hands. Massage lather onto skin with a gentle, circular motion for 20 to 30 seconds. Rinse thoroughly and gently pat dry. Follow with ACTIV O2 Acne Treatment Lotion or Cream. • avoid contact with eyes, lips and mouth

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

Butylated Hydroxytoluene, Disodium Edetate, Glycerin, Jojoba (Simmondsia Chinensis) Seed Oil, Olive (Olea Europaea) Fruit Oil, Sodium Lauryl Sulphate, Sodium Palmitate, Sodium Palm Kernelate

#### ***Other information***

• store below 25 °C

## Questions?

+1-917-676-2004 Available during working hours: (9am – 5pm) Monday to Friday

Manufactured by: ACTIV OZONE (Pty) Ltd.

77, 10th Road, Kew, Johannesburg, South Arica, 2090. Tel: +27-11-887-1752. [www.activo2.com](http://www.activo2.com)

**Made in South Africa**

**Distributed / Imported / Marketed by:**

Miller Methods Imports, 3921 Alton Road, Miami Beach FL, 33140

**You may report serious side effects to the above address**

INSPIRED BY NATURE

PERFECTED BY SCIENCE

FRAGRANCE FREE

## Packaging



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<b>Drug Facts (continued)</b>	
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<b>Drug Facts (continued)</b>	
<b>Questions?</b> +1-917-676-2003 Available during working hours: (9am - 5pm) Monday to Friday Manufactured by: ACTIV OZONE (Pty) Ltd. 77, 10th Road, Kew, Johannesburg, South Africa, 2090. Tel: +27-11-887-1752. <a href="http://www.activo2.com">www.activo2.com</a>	
<b>Made in South Africa</b>	
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## ACTIV O2 ACNE TREATMENT CLEANSING BAR

salicylic acid soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71577-111
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	2 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
GLYCERIN (UNII: PDC6A3C0OX)				
JOJOBA OIL (UNII: 724GKU717M)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM PALMITATE (UNII: JQ43KP6296)				
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71577-111-12	125 g in 1 CARTON; Type 0: Not a Combination Product	09/28/2017	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	09/28/2017		

**Labeler** - Activ Ozone (pty) Ltd (539181712)

### Establishment

Name	Address	ID/FEI	Business Operations
Activ Ozone (pty) Ltd		539181712	manufacture(71577-111)

Revised: 9/2017

Activ Ozone (pty) Ltd