

ACTIV O2 ACNE TREATMENT CREAM- sulfur cream

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.

ACTIV O2 ACNE TREATMENT CREAM

Drug Facts

Active ingredient

Sulfur (10%)

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.

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 •avoid unnecessary sun exposure and use a sunscreen after using this product •skin irritation may occur such as redness, burning, itching and peeling •do not use on broken skin

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

- clean the skin thoroughly before applying this product.
- cover the entire affected area with a thin layer 1 to 3 times a day.
- if bothersome dryness or peeling occurs, reduce application to daily.

Sensitivity Test for a New User. 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

Cetearyl Alcohol, Disodium EDTA, Ethylhexyl Cocoate, Fragrance (Parfum), Jojoba (Simmondsia Chinensis) Seed Oil, Olive (Olea Europaea) Fruit Oil, Phenoxyethanol, Polysorbate 20, Potassium Cetyl Phosphate, PPG-3 Benzyl Ether Myristate, Sodium Polyacrylate, Water (Aqua)

Other information

- store below 25 °C

Questions?**+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. 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

ADVANCED SCIENTIFIC FORMULATION

Packaging



ACTIV O2 ACNE TREATMENT CREAM

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71577-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70 FD1KFU70) (SULFUR - UNII:70 FD1KFU70)	SULFUR	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYL COCOATE (UNII: I1MPW273QS)	
JOJOBA OIL (UNII: 724GKU717M)	

OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71577-222-50	1 in 1 CARTON	09/27/2017	
1		50 mL in 1 JAR; 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	09/27/2017	

Labeler - Activ Ozone (pty) Ltd (539181712)

Establishment

Name	Address	ID/FEI	Business Operations
Activ Ozone (pty) Ltd		539181712	manufacture(71577-222)