

ROSAACNE RELIEF- sulfur, salicylic acid ointment

Kunming Zhongzhou Pharmaceutical Co, 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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Active Ingredients

Sulfur 7.1%
Salicylic Acid 3%

Purpose

Acne Treatment

Uses

For the treatment of acne

Warning

For external use only.

When using this product

1. Some patients may have aggravated symptoms within 10 days of use; but may start to improve after 2 weeks.
2. The product is recommended to use continuously without interruption.
3. Skin irritation and dryness are likely to occur if you use another topical acne medication at the same time. If irritation occurs, use only one topical acne product at a time.
4. Pregnant or breast-feeding women and children use with caution.
5. Avoid contact with eyes.
6. If dryness, slight burn feeling or skin peeling occurs, reduce application and use one time a day or every other day.

Do not use

If you are allergic to any ingredient(s) of the product.

Keep out of reach of children.

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

Directions

Cleanse the skin thoroughly before applying this product twice a day.

Storage

Keep in a dry, cool place away from direct sunlight.

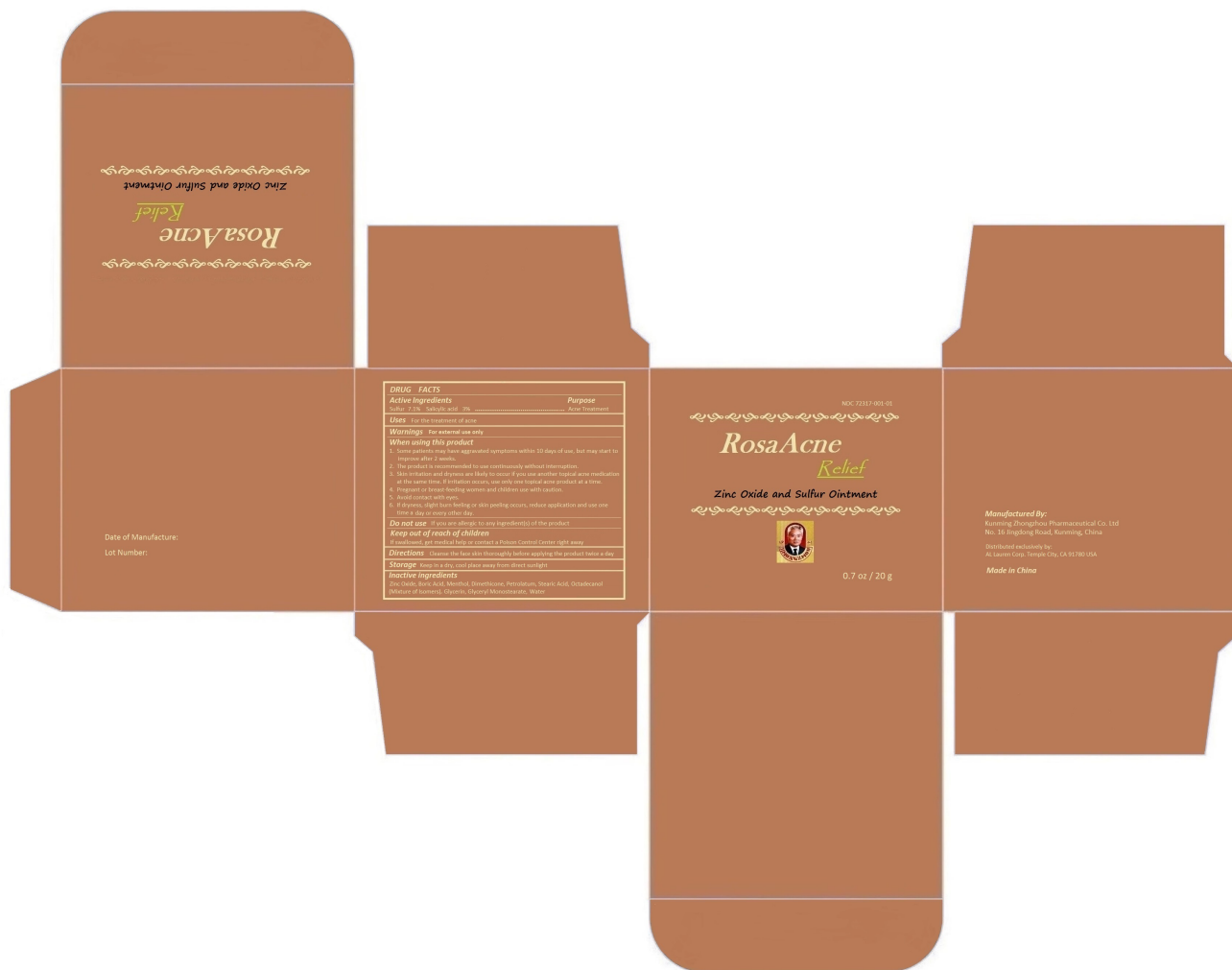
Manufactured by:
Kunming Zhongzhou Pharmaceutical Co. Ltd
No. 16 Jingdong Road, Kunming, China
Made in China

Distributed exclusively by:
 AL Lauren Corp. Temple City, CA 91780 USA

Inactive Ingredients

Zinc Oxide, Boric Acid, Menthol, Dimethicone, Petrolatum, Stearic Acid, Octadecanol (Mixture of Isomers), Glycerin, Glyceryl Monostearate, Water

Drug Facts



ROSAACNE RELIEF
 sulfur, salicylic acid ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72317-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	7.1 g in 100 g
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Zinc Oxide (UNII: SOI2LOH54Z)	
Boric Acid (UNII: R57ZHV85D4)	
Menthol (UNII: L7T10EIP3A)	
Dimethicone (UNII: 92RU3N3Y1O)	
Petrolatum (UNII: 4T6H12BN9U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
OCTADECANOL (MIXTURE OF ISOMERS) (UNII: C6BPY2QY39)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72317-001-01	1 in 1 BOX	07/18/2018	
1		20 g in 1 BOTTLE, PLASTIC; 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	07/18/2018	

Labeler - Kunming Zhongzhou Pharmaceutical Co, Ltd (529561942)

Revised: 7/2018

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