# ASSURED ACNE CREAM - acne cream cream HANGZHOU MINO DAILY CHEMICALS 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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## **Drug Facts**

## **Active Ingredient**

Salicylic Acid 0.5%

#### **Purpose**

#### **Acne Treatment**

#### Warnings

#### For external use only

- flammable, keep away from fire and flame
- will produce serious gastric disturbances if taken internally

Ask a doctor before use if you have deep puncture wounds or serious burns

## When using this product

- do not get into eyes or mucous membranes
- use only in a well-ventilated area

**Stop use and ask a doctor if** condition persists or gets worse.

**Keep out of reach of children.** In case of an accidental ingestion, contact a Poison Control Center immediately.

#### Use

for the treatment of acne.

For external use only.

**Do not use** if you have very sensitive skin or are sensitive to Salicylic Acid.

**Ask a doctor or pharmacist before use if you are** using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

**When using this product**, avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth.

**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 medication. Apply cream directly on acne pimples.

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 as directed by a doctor. If bothersome occurs, reduce application to once a day.

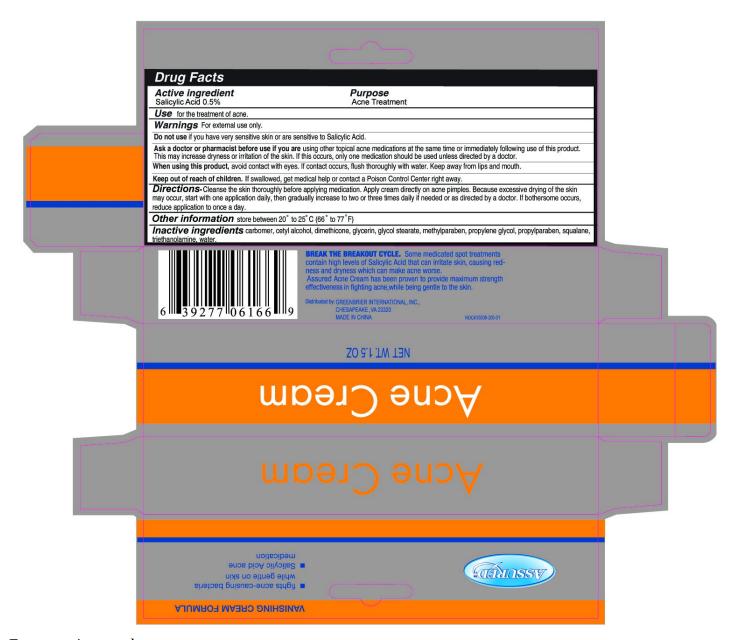
#### Other information

store between 20 to 25 C (66 to 77 F)

#### **Inactive ingredients**

carbomer, cetyl alcohol, dimethicone, glycerin, glycol stearate, methylparaben, propylene glycol, propylparaben, squalane, triethanolamine, water.

#### **Package Label**



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acne cream cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35038-200	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	.5 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	74.5 mL in 100 mL		
SQUALANE (UNII: GW89575KF9)	10 mL in 100 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	5 mL in 100 mL		
CETYL ALCOHOL (UNII: 936JST6JCN)	3.5 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL		
GLYCOL STEARATE (UNII: 0324G66D0E)	2 mL in 100 mL		
DIMETHICO NE (UNII: 92RU3N3Y1O)	1 mL in 100 mL		
METHYLPARABEN (UNII: A2I8C7HI9T)	.2 mL in 100 mL		
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	.1 mL in 100 mL		
TROLAMINE (UNII: 903K93S3TK)	.1 mL in 100 mL		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35038-200-01	44 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	06/01/2010		

## Labeler - HANGZHOU MINO DAILY CHEMICALS CO.LTD. (527974203)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
HANGZHOU MINO DAILY CHEMICALS CO.LTD.		527974203	manufacture

Revised: 12/2010 HANGZHOU MINO DAILY CHEMICALS CO.LTD.