

**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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ASSURED ACNE CREAM

acne cream cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35038-200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	.5 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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
DIMETHICONE (UNII: 92RU3N3Y1O)	1 mL in 100 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	.2 mL in 100 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	.1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	.1 mL in 100 mL

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:35038-200-01	44 mL in 1 TUBE		

**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 final	part333D	06/01/2010	

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

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

Revised: 12/2010

HANGZHOU MINO DAILY CHEMICALS CO.LTD.