

## **ACNE TREATMENT- salicylic acid gel**

**Natureplex LLC**

*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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### **Acne Treatment**

#### ***Drug Facts***

#### **Active ingredient**

Salicylic Acid 0.5%

#### **Purpose**

Acne Treatment

#### **Use**

For the treatment of acne.

#### **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.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

#### **Directions**

- *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 below
- clean the skin thoroughly before applying this product
- cover entire affected area with a thin layer 1 to 3 times daily
- because excessive drying of skin may occur, start with one application daily, and gradually increase to 2 or 3 times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

#### **Other information**

- store at 15 to 30°C (59 to 86°F)
- close cap tightly after use
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

#### **Inactive ingredients**

citric acid, sodium phosphate dibasic, DMDM hydantoin, glycerin, hydroxyethylcellulose, isopropyl

alcohol, methylparaben, polysorbate-20, propylene glycol, propylparaben, purified water

**Questions or comments?**

**866-323-0107 or [www.natureplex.com](http://www.natureplex.com)**

**PRINCIPAL DISPLAY PANEL - 42.5 g Tube Box**

*Natureplex™*

*Acne*

*Treatment*

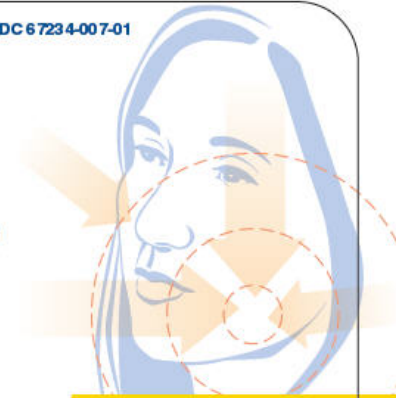
*Clear Gel*

**NET WT. 1.5 Oz.(42.5g)**

NDC 67234-007-01

Natureplex

# Acne Treatment Clear Gel



\* Compare to the active ingredient of Neutrogena®



- Reduces Breakouts
- Non-Greasy Gel
- Salicylic Acid Acne Treatment



3057B V14

Acne Treatment Clear Gel

Natureplex

# Acne Treatment Clear Gel



NET WT. 1.5 Oz. (42.5g)

Natureplex

# Acne Treatment Clear Gel



\* This product is not manufactured for or distributed by Neutrogena Corporation, the distributor of Neutrogena Acne Treatment®.

NATUREPLEX, Olive Branch, MS 38654 • 1-866-323-0107

MADE IN THE USA

Natureplex

<b>Drug Facts</b>
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<b>Purpose</b> Acne Treatment
<b>Use</b> For the treatment of acne.
<b>Warnings</b> 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. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222
<b>Directions</b> 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 below. ■ clean the skin thoroughly before applying this product. ■ cover entire affected area with a thin layer 1 to 3 times daily. ■ because excessive drying or skin may occur, start with one application daily, and gradually increase to 2 or 3 times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
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<b>Inactive ingredients</b> dicitr acid, sodium phosphate dibasic, DMDM hydantoin, glycerin, hydroxyethylcellulose, isopropyl alcohol, methylparaben, polysorbate-20, propylene glycol, propylparaben, purified water.
<b>Questions or comments?</b> 866-323-0107 or <a href="http://www.natureplex.com">www.natureplex.com</a>



Acne Treatment Clear Gel

salicylic acid gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67234-007
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%) (UNII: L605B5892V)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-007-01	1 in 1 BOX	01/02/2007	
1		42 g in 1 TUBE; 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	01/02/2007	

**Labeler** - Natureplex LLC (062808196)

### Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-007)