

## ACNI SPOT - acni spot liquid

La Jolla

*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

Salicylic Acid 2% Acne Treatment

When using this product avoid contact with eyes. If contact occurs, immediately flush with water.

Warnings: Foreexternal use only.

Do not use if using other topical acne medications at the same time or immediately following use of this product as it may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a physician.

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. Cover the entire affected area with a thin layer one to three times daily. 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 dryness or peeling occurs, reduce application to once a day or every other day.

Other Ingredients: Water, SD Alcohol 40-B, Glycolic Acid, Urea, Propylene Glycol, Ammonium Glycolate, Allantoin, Bisabolol, Nonoxynol-9, Disodium EDTA

pictures

ACNE THERAPY SYSTEM

step 3



ACNE SPOT TREATMENT

#### Drug Facts

Active Ingredient	Purpose
Salicylic Acid 2%	Acne Treatment

Uses	for the treatment of acne
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York-Goldman Enterprises, Inc.

[www.coolclenz.com](http://www.coolclenz.com)

La Jolla, California 92037

Questions? **800.886.5318**

0.5 Fl. Oz. (15mL)

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**ACNI SPOT**

acni spot liquid

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35658-000
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1.93 mL in 96.5 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35658-000-03	25 in 1 CASE		
1		15 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/01/2009	

**Labeler** - La Jolla (021918650)**Registrant** - Harmony Labs, Inc. (105803274)**Establishment**

Name	Address	ID/FEI	Business Operations
Harmony Labs, Inc.		105803274	manufacture, label, pack, relabel, repack

Revised: 5/2010

La Jolla