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.

Drug Fcts

Salicylic Acid 2% Acne Treatment

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

Warnings: Forexternal 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.

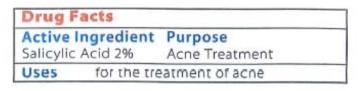
If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times dally. 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 AlcohoI40-B. Glycolic Acid, Urea, Propylene Glycol, Ammonium Glycolate, Allantoin, Bisabolol, Nonoxynol-9. Disodium EDTA pictures









York-Goldman Enterprises, Inc. www.coolclenz.com

La Jolla, California 92037 Questions? **800.886.5318**

0.5 Fl. Oz. (15mL)

Drug Facts continued

Warnings: For external use only.

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When using this product

Avoid contact with eyes. If contact occurs, immediately flush with water.

Keep out of reach of children.

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Directions:

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Active Ingredient: Salicylic Acid 2%

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

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
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)
Salicylic Acid
1.93 mL in 96.5 mL

Packaging

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#	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