# GLYCARE ACNE - glycolic acid gel MD Formulation

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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# **Glycare Acne Gel**

Salicylic Acid 1%

Acne Tratment

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

Clears up acne blemishes and helps prevent new acne blemishes.

For external use only.

Directions Cleanse skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1 to 3 times dally. Because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a physician. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Water (aqua), sd alcohol 40-b, glycolic acid, ammonium glycolate, hydroxypropyl melhylcellulose.

# **Drug Facts**

Active Ingredient Salicylic Acid 1%

Purpose Acne Treatment

Uses Clears up acne blemishes and helps prevent new acne blemishes.

Warnings For external use only.

When using this product Avoid unnecessary sun exposure and use sunscreen. Keep away from eyes, lips and mouth. This product may cause irribation, characterized by redness, burning, thehing, peeling or possible swelling. More frequent use or higher concentrations may aggravate such initiation.

Stop use and ask a doctor if Condition worsens or does not improve after regular use.

Keep out of reach of children If swallowed, get medical help or contact a Polson Control Center right away.

See Carton for complete information

NDC-96078-035-25

glycare acne gel acne medication clarifies, exfoliates and refines

gel purifiant purifiant, exfoliant et adoucissant

75 ml (2.5 fl. oz.)

md formulations\*

Dist. by md formulations<sup>®</sup>
San Francisco. CA 94105 USA
Bare Escantulas UK Ltd., S313 TND. UK
www.mdiarmulations.com
Made in USA \* 30837

# md formulations'



**→**[[]] Ce gel léger permet d'extolier et d'érminer les cellules modes laissant alss la poau plus douce et nette. Adouct et affine le grain de la peau fout en évitant l'apparation d'imperfections.

- compose plyacique 5 %
   acide salloylique 1 %
   pH équilibré (pH 3,8)
   lesis sous contrôte demotologique
   non-comédogène
   hypoollegienque
   sons parlum

Utilisation: Après over neltoyé la peau, appliquer une faible quantité de gel sur les zones conences, une à trace tos par jour. Un dessèchement excessif de la peau peut survenir. Dans ce cas, commence pour une suple proflection.

ia peau peur sorvenir. Dans de cas, commencer por une seule application qualidienne. Puis, procéder petit à petit à deux au histo application por jour. Si la peau devient excessivement sèche et commence à peter, réduire le nombre d'application à une par jour au une tous les deux jours.

une rous les deux jours.

Précaullons d'emploi: À usage externe uniquement. Éviter fout contact avec les yeux. En cos d'irritation, rincer abondamment, interrompre l'utilisation du produit et consulter un médecin. Utiliser un écron solaire SPF-15 (ou d'indice supérieur) ofin d'éviter fout risque de photosensibilisation.

NDC 66078-035-25

# md formulations\*

glycare acne gel acne medication clarities, exfoliates problem-prone skin contains glycolic acid

gel purifiant purifiant, exfoliant et adoucissant peaux grasses et à problèmes contient de l'acide glycolique

75 ml (2.5 fl. oz.)

Esta fórmula gelificada de rápida ab-sorción exfolia los cétulas superficiales de la piet revelando un cults más suave y limpio. Purifica y suaviza la piet a la vez que aryuda a prevenir la aportación de futuras imperiecciones.

- compusto glipólico al 5%
   ácido salicifico al 1%
   pH balanceado (pH 3,8)
   dermatológicamente testeado
   no comedogénico
   hipoplergénico

• libra de regencia
Modo de uso: Limple la piel. Cubra los zonas disclados con una capa delgado de quel de una a tres veces por dia (Como la piel puede researce excesivamente, es coonsejoble comentazar con una aplicación diaria. Si es necesario, aumente graducimente las opticaciones a des a tres veces por dia. Si la piel se researca o se descuma excesivamente, reduzca los aplicaciones a una vez al dia o caballa. Si la consultar dia contra de la contra del contra de la con

Advertencia: Sólo para uso externo. Advertencia: Solo para uso externo. Evite que penête en las ojos. Si produce irrilación, enjuague bien el producto, suspenda su uso y consulte a un médico. Use profector solar con un factor de profección de 15 ó más para prevenir cualquier aumento en la sensibilidad al sol.

# US PROFESSIONAL TREATMENT

### **Drug Facts**

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Purpose Acne Treatment

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Control Center right away.

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Other information store at 20-25°C (68-77°F)

Inactive ingredients Water (aqua), sd alcohol 40-b, glycolic acid, ammonium glycolate, hydroxypropyl methylcellulose.

Dist. by **md** formulations<sup>®</sup>
San Francisco, CA 94105 USA
Bare Escentuals UK Ltd., SS13 1ND, UK www.mdformulations.com Made in USA • 30837

## **GLYCARE ACNE**

glycolic acid gel

## **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66078-035

Route of Administration

TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) **Basis of Strength** 

Strength

SALICYLIC ACID

1 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCOLIC ACID (UNII: 0 WT12SX38S)				
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78 RG6 M2N2)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:66078-035-25	54 in 1 CASE					
1		1 in 1 CARTON					
1		72 g in 1 TUBE					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part333D	10/07/2001					

# Labeler - MD Formulation (087008363)

# Registrant - Harmony Labs, Inc. (105803274)

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

Revised: 7/2011 MD Formulation