

KLEARACTIL- acne topical treatment gel
POLIMEROS Y SERVICIOS S.A.

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.

Submission for Klearactil Acne Topical Treatment

Detail showing Active Ingredient from package

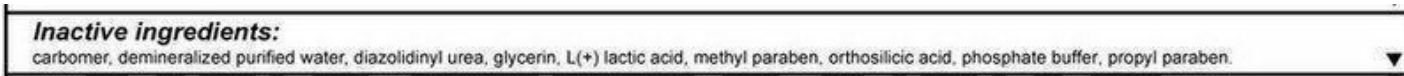
Active ingredients_001.jpg



Information shown both on container label and package

Detail showing Inactive ingredient from package

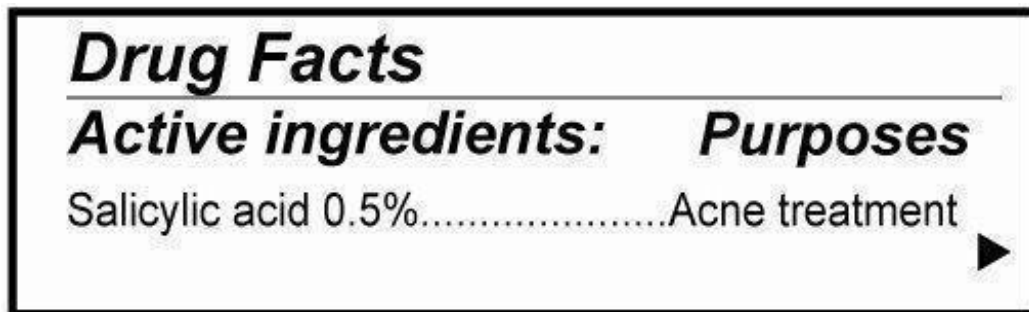
Inactive ingredients.jpg



Information shown both on container label and package

Detail showing Purpose within Active Ingredients from package

Purpose.jpg




Information shown both on container label and package

Detail showing Instructions for use and named Directions from package

indications_001.jpg

Drug Facts

Indications:

- For the treatment of acne. ■ Clears acne pimples, acne blemishes, blackheads and whiteheads and allows skin to heal.
 - Helps prevent new acne pimples, acne blemishes, blackheads and whiteheads from forming.
- 


Information shown both on container label and package

Detail showing Dosage and Administration within Directions from package

Dosage and administration.jpg

Drug Facts (continued)

Directions:

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply externally to the affected area up to six times daily or after each bowel movement.
 - Children under 12 years of age: Consult a physician.
- 

Information shown both on container label and package

Detail showing Warnings from package

Warnings.jpg

Drug Facts (continued)

Warning:

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.

- **For external use only.**

Keep out of reach of children.



Information shown both on container label and package

Detail showing Keep Out of Reach of Children within Warnings from package

Keep out of reach of Childreb.jpg


Drug Facts (continued)

Warning:

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.

■ **For external use only.**

Keep out of reach of children.



Information shown on package

Detail showing Questions from package


Questions.jpg

Questions or comments? Call weekdays 9 am to 5 pm CST 1-888-621-1255 or 1-832-877-3784. 

Information shown both on container label and package

etail showing Other Safety Information from package

Other safety information.jpg

Other information: Best if stored between 40° F and 90° F 

Information shown both on container label and package

Representative sample image of carton/container label

Container label.jpg

Directions:

- clean the skin thoroughly before applying this product
- 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 Information: Best if stored between 40° F and 90° F

Inactive ingredients: carbomer, demineralized purified water, diazolidinyl urea, glycerin, L(+) lactic acid, methyl paraben, orthosilicic acid, phosphate buffer, propyl paraben.

Questions or comments? Call weekdays 9 am to 5 pm CST **1-888-621-1255 or 1-832-877-3784** ☎



Net Weight: 1.06 oz (30g)

Drug Facts

Active ingredients	Purposes
Salicylic acid 0.5%.....	Acne treatment

Indications:

- For the treatment of acne.
- Clears acne pimples, acne, blemishes, blackheads and whiteheads and allows skin to heal.
- Helps prevent new acne pimples, acne blemishes, blackheads and whiteheads from forming.

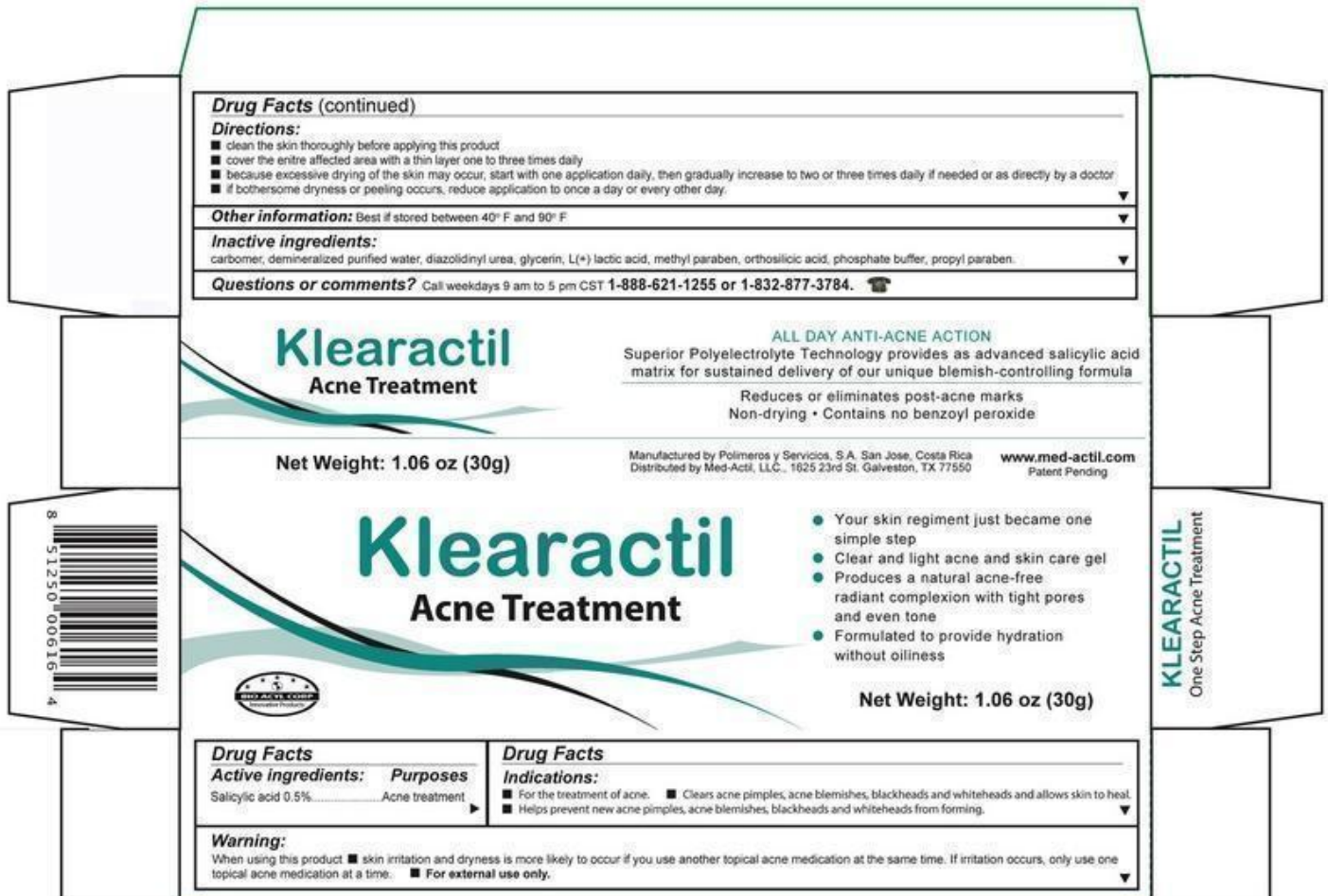
Do Not Use if seal under cap is broken or missing. This package contains an outer carton. Do not buy if outer carton is missing.

Manufactured by Polimeros y Servicios, S.A. San Jose, Costa Rica
Distributed by Med-Actil, LLC. 1625 23rd St. Galveston TX 77550
www.med-actil.com

Warning:
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. ■ **For external use only.**

General view of inner container label

Package label.jpg



Drug Facts (continued)

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Klearactil Acne Treatment

Net Weight: 1.06 oz (30g)

ALL DAY ANTI-ACNE ACTION
Superior Polyelectrolyte Technology provides as advanced salicylic acid matrix for sustained delivery of our unique blemish-controlling formula

Reduces or eliminates post-acne marks
Non-drying • Contains no benzoyl peroxide

Manufactured by Polimeros y Servicios, S.A. San Jose, Costa Rica
Distributed by Med-Actil, LLC. 1625 23rd St. Galveston, TX 77550 www.med-actil.com
Patent Pending

Klearactil Acne Treatment

- Your skin regiment just became one simple step
- Clear and light acne and skin care gel
- Produces a natural acne-free radiant complexion with tight pores and even tone
- Formulated to provide hydration without oiliness

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KLEARACTIL
One Step Acne Treatment

General view of box content of labeling

KLEARACTIL

acne topical treatment gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69492-012
Route of Administration	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
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, L- (UNII: F9S9FFU82N)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ORTHO SILICIC ACID (UNII: 623B93YABH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69492-012-20	1 in 1 BOX	03/04/2019	
1	NDC:69492-012-05	30 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	06/29/2015	

Labeler - POLIMEROS Y SERVICIOS S.A. (815740251)

Establishment

Name	Address	ID/FEI	Business Operations
POLIMEROS Y SERVICIOS S.A.		815740251	manufacture(69492-012)