KERACTIL PLUS- antifungal 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 KERACTIL Plus Topical Antifungal Gel

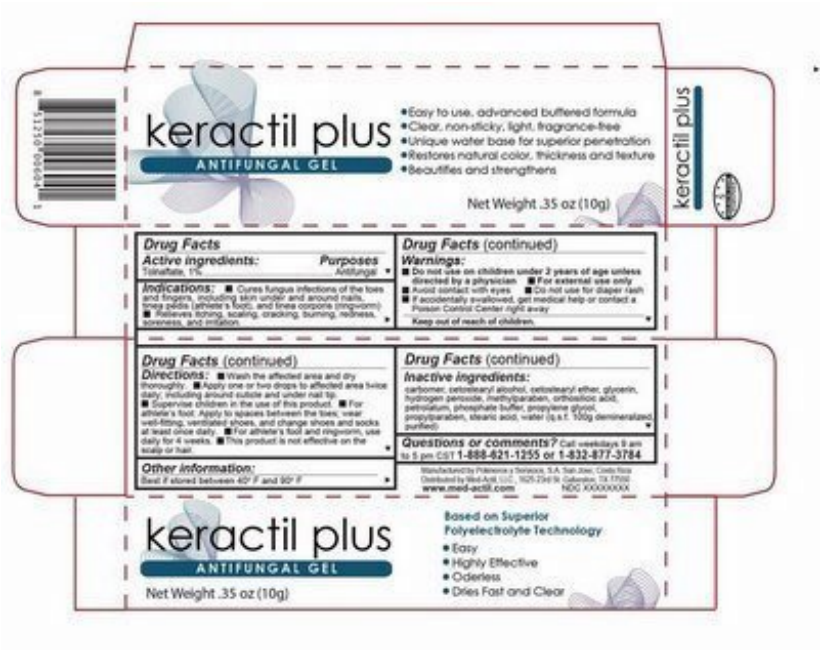
Representative sample image of carton/container label

General view of box content of labeling

Caja con cambios Keractil Plus.jpg

Representative sample image of carton/container label

Keractil Fondo gris.jpg



Detail showing Active Ingredient from package

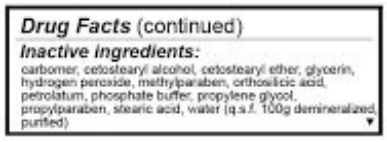
Information shown both on container label and package

Active Ingredients- Keractil plus.jpg

Detail showing Inctive Ingredient from package

Infiomaion shown both on content of label and package

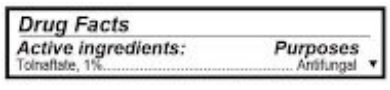
Inactive ingredients.jpg



Detail showing Purpose within Active Ingredients from package

Information shown both on container label and package

Purpose.jpg



Detail showing Instructions for use and named Uses from package

Ibformation shown both on container label and package

Directions.jpg

Detail showing Dosage and Administration within Directions from package

Information shown both on container label and package

Dosage and administration.jpg

Detail showing Warnings from package

Information shown both on cintainer label and package

Warnings-.jpg

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

Information shown both on cobtainer label and package

Keep out of reach of children.jpg

Detail showing Questions from package

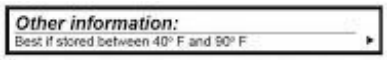
Information shown both on container label and package

Questions Keractil Plus.jpg

Detail showing Other Safety Information from package

Ibformation shown both on container label and package

Other information Keractil plus.jpg



KERACTIL PLUS

antifungal gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69492-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ORTHOSILICIC ACID (UNII: 623B93YABH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69492-014-06	1 in 1 BOX	03/04/2019	
1		10 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	part333C	03/09/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
POLIMEROS Y SERVICIOS S.A.		815740251	manufacture(69492-014)

Revised: 3/2019 POLIMEROS Y SERVICIOS S.A.