POLYACTIL N- skin protectant 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 Polyactil-N Skin Pritectant

Detail showing Active Ingredient from package

Information shown both on container label and paclage



Drug fact active ingredients -.jpg

Detail showing Inactive ingredient from package

Information shown both on cntainer label and package

Inactive ingredients:

Carbopol, diazolidinyl urea, glycerin, methyl paraben, orthosilicic acid, phosphate buffer, propyl paraben, water (q.s.f. 100g demineralized, purified), xylitol.

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



Inactive ingredients-.jpg

Detail showing Purpose within Purposes from package

Information shown both on container label and package

Drug Facts		94
Active ingredients:	Purposes	
Allantoin 0.5%	Skin Protectant	•

Purpose .jpg

Detail showing Indications from pacage

Information shown both on container label and package Indicationss.jpg

Uses:

Temporarily protects minor ■ cuts ■ scrapes ■ burns. ■ Helps prevent, relieve and temporarily protect chafed, chaped or cracked skin and lips. ■ Helps prevent and protect from the drying effects of wind and cold weather.

Detail shyowing Instructions for use and named Directions from package

Information shown both on container label and package

Drug Facts (continued)

Directions:

Apply thin layer to affected area as needed. Best to apply as soon as possible after injury or damage. May be applied as often as needed.

Drug Fast (continued).jpg

Detail showing Dosage abd Administration within Directions from package

Information shown both on container lable and package

Drug Facts (continued)

Directions:

Apply thin layer to affected area as needed. Best to apply as soon as possible after injury or damage. May be applied as often as needed.

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Dosage and ad.jpg

Detail showing Warnings from package

Information shown both on container label and package

Drug Facts

Warnings:

- When using this product, do not get into eyes
- Stop using and ask a doctor if condition worsens symptoms last more than 7 days or clear up and occur again within a few days
- For external use only

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

Drug Facts Warnings.jpg

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

Information shown on package

Drug Facts

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Keep out of reach of chilfren.jpg

Detail showing Questions from package

Information shown on package

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



Questions or comments.jpg

Detail showing Other Safety Information from package

Information shown both on container label and package

Other information:

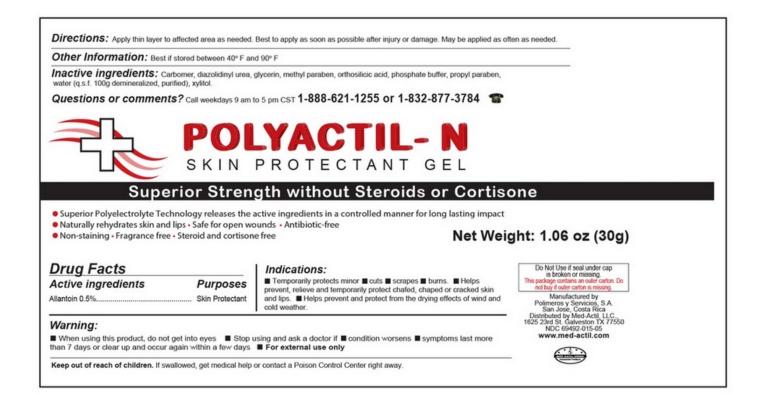
Best if stored between 40° F and 90° F

Other informations-.jpg

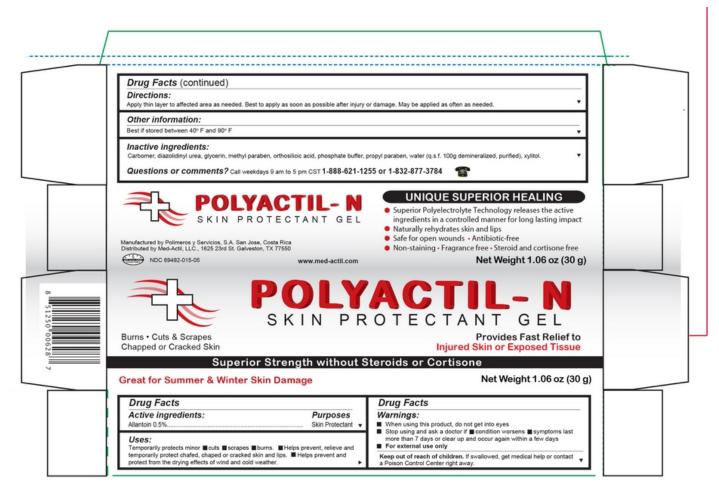
Representative sample image of carton/container label

General view of inner container label

Etiqueta de Polyactil - N Lunes 20 06 16.jpg



General view of box content of labeling



POLYACTIL N

skin protectant gel

Droduct	Information
Product	HUHUTHIAUUH

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:69492-015
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	retive ingredient/retive tyrotety		
l	Ingredient Name	Basis of Strength	Strength
l	ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 g

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) CARBOMER 940 (UNII: 4Q93RCW27E) ORTHOSILICIC ACID (UNII: 623B93YABH) SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74) XYLITOL (UNII: VCQ006KQ1E) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) METHYLPARABEN (UNII: A218C7H19T) PROPYLPARABEN (UNII: Z81X2SC10H) WATER (UNII: 059QF0KO0R)

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:69492-015-05	1 in 1 BOX	06/20/2016	
l	1	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	part347	06/20/2016	

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

Establishment			
Name	Address	ID/FEI	Business Operations
POLIMEROS Y SERVICIOS S.A.		8 15740 251	manufacture (69492-015)

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