

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 Facts	
Active ingredients:	Purposes
Allantoin 0.5%.....	Skin Protectant ▼

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	
Active ingredients:	Purposes
Allantoin 0.5%.....	Skin Protectant ▼

Purpose .jpg

Detail showing Indications from pacage

Information shown both on container label and package

Indications.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 showing 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 and Administration within 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. ▼

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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 - **For external use only**
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Keep out of reach of children.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

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.

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

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

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POLYACTIL- N

SKIN PROTECTANT GEL

Superior Strength without Steroids or Cortisone

- Superior Polyelectrolyte Technology releases the active ingredients in a controlled manner for long lasting impact
- Naturally rehydrates skin and lips • Safe for open wounds • Antibiotic-free
- Non-staining • Fragrance free • Steroid and cortisone free

Net Weight: 1.06 oz (30g)

Drug Facts

Active ingredients

Allantoin 0.5%.....

Purposes

Skin Protectant

Indications:

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

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. NDC 69492-015-05

www.med-actil.com



Warning:

■ 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

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General view of box content of labeling

Drug Facts (continued)
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Other information:
Best if stored between 40° F and 90° F

Inactive ingredients:
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UNIQUE SUPERIOR HEALING

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Net Weight 1.06 oz (30 g)

POLYACTIL- N
SKIN PROTECTANT GEL

Burns • Cuts & Scrapes
Chapped or Cracked Skin

Provides Fast Relief to
Injured Skin or Exposed Tissue

Superior Strength without Steroids or Cortisone

Great for Summer & Winter Skin Damage **Net Weight 1.06 oz (30 g)**

Drug Facts
Active ingredients:
Allantoin 0.5%.....
Purposes
Skin Protectant

Uses:
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POLYACTIL N

skin protectant gel

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ORTHO SILICIC ACID (UNII: 623B93YABH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
XYLITOL (UNII: VCQ006KQ1E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69492-015-05	1 in 1 BOX	06/20/2016	
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.		815740251	manufacture(69492-015)