

**PRANICURA 5- glycerin, kaolin, calamine, menthol cream**  
**Pranicura Products LLC**

-----  
**PRANICURA 5**

**Drug Facts**

Active Ingredients

Glycerin	25%
Kaolin	12.5%
Calamine	12.5%
Menthol	1%

**Purposes**

Glycerin	.....Protectant
Kaolin	.....Protectant/Anti-Itch
Calamine	.....Protectant/Anti-Itch
Menthol	.....Analgesic

**Uses** • Helps relieve the itching and discomfort associated with anorectal disorders • Provides temporary relief from the symptoms of perianal skin irritation • For the temporary relief of itching associated with moist anorectal conditions • For the temporary relief of irritation and burning

**Warnings**

**For rectal use only**

**Do not use** unless a prior doctor's diagnosis of anorectal condition has been made

**When using this product** do not exceed the recommended daily dosage unless directed by a doctor

**Stop use and ask a doctor if** • bleeding occurs • condition worsens or does not improve within 7 days • allergic reaction develops • symptoms being treated do not subside or if redness, irritation, swelling, pain, other symptoms develop or increase • Do not put this product into the rectum by using fingers or any mechanical device or applicator.

• Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area

**If pregnant or breastfeeding**, ask a health professional before use

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

**Other Information** store at 15-30° C (59-86° F)

**Other Information** store at 15-30° C (59-86° F)

**Inactive Ingredients**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cetearyl Alcohol, Deionized Water, Dimethicone/Vinyl Dimethicone Crosspolymer, Isopropyl Palmitate, Magnesium Aluminum Silicate, Phenoxyethanol, Polysorbate 20, Propylene Glycol, SD Alcohol, Silica, Stearyl Alcohol

**Questions or Comments?** Call weekdays 9 AM to 5 PM CST at 763-537-3419

**PRANICURA 5**

*Ultimate Relief from Pruritus Ani, Fissures and Hemorrhoids*

Available only at: [www.pranicura.com](http://www.pranicura.com)

Net Wt. 2.1 oz. (60 g)

6.5 in

**TOP**

Fonts on top label (and underlying labels) are at least 6pt or larger.

**PRANICURA 5**

*Ultimate Relief from Pruritus Ani, Fissures and Hemorrhoids*

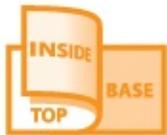
Available only at: [www.pranicura.com](http://www.pranicura.com)  
Net Wt. 2.1 oz. (60 g)

**Drug Facts**

Active Ingredients	Purposes
Glycerin 25%.....	Protectant
Kaolin 12.5%.....	Protectant/Ani-Itch
Calamine 12.5%.....	Protectant/Ani-Itch
Menthol 1%.....	Analgesic

Uses: • Helps relieve the itching and discomfort associated with anorectal disorders • Provides temporary relief from the symptoms of perianal skin irritation • For the temporary relief of itching associated with moist anorectal conditions • For the temporary relief of irritation and burning

PULL HERE



Multi-Layer Label

**250354**

PROOF# **10**

SS  
30  
HD175

**INSIDE**

**Drug Facts (continued)**

**Warnings**  
For rectal use only  
Do not use unless a prior doctor's diagnosis of anorectal condition has been made  
When using this product do not exceed the recommended daily dosage unless directed by a doctor  
Stop use and ask a doctor if • bleeding occurs • condition worsens or does not improve within 7 days • allergic reaction develops • symptoms being treated do not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase  
• Do not put this product into the rectum by using fingers or any mechanical device or applicator.

**Drug Facts (continued)**

• Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area  
If pregnant or breastfeeding, ask a health professional before use  
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

• Adults: When practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

----- Indicates copy safe area  
(No ink can extend beyond dotted lines)

**BASE**

**Drug Facts (continued)**

• For Pruritus Ani: Wait 20 seconds after drying. If the desire to scratch is gone, do not apply cream. If the desire to scratch continues, apply a fingertip amount of ointment to anal and perianal areas. Use finger cot or disposable gloves if desired. Rub or lightly scratch (with fingertip, not fingernails) until the itch is satisfied.  
• For Anal Fissures: Apply a fingertip amount of cream to the anal area and to the inner rim of the anus.  
• Children under 12 years of age: consult a doctor  
• Apply externally to the affected area once or twice daily when pain or irritation from anal fissures are present or ideally after bowel movement

**Drug Facts (continued)**

Other information: store at 15-30°C (59-86°F)  
**Inactive Ingredients:**  
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cetearyl Alcohol, Deionized Water, Dimethicone/Methyl Dimethicone Crosspolymer, Isopropyl Palmitate, Magnesium Aluminum Silicate, Phenoxyethanol, Polysorbate 20, Propylene Glycol, SD Alcohol, Silica, Stearyl Alcohol

Questions or Comments? Call weekdays 9 AM to 5 PM CST at 763-537-3419

Manufactured for Pranicura LLC by Pure Source LLC,  
9750 NW 17th St., Miami, Florida 33172

# PRANICURA 5

Ultimate Relief from Pruritus Ani, Fissures and Hemorrhoids

Available only at: [www.pranicura.com](http://www.pranicura.com)  
Net Wt. 2.1 oz. (40 g)

## Drug Facts

### Active Ingredients

Glycerin 20%	Protectant
Kaolin 12.5%	Protectant/Anal-An
Calamine 12.5%	Protectant/Anal-An
Menthol 1%	Anesthetic

### Purposes

Uses • Helps relieve the itching and discomfort associated with anorectal disorders • Provides temporary relief from the symptoms of perianal skin irritation • For the temporary relief of itching associated with most anorectal conditions • For the temporary relief of irritation and burning

PULL HERE

## Drug Facts (continued)

### Warnings

For rectal use only

Do not use unless a prior doctor's diagnosis of anorectal condition has been made

When using this product do not exceed the recommended daily dosage unless directed by a doctor

Stop use, and ask a doctor if • bleeding occurs • condition worsens or does not improve within 7 days • allergic reaction develops • symptoms being treated do not subside or if redness, irritation, swelling, pain, other symptoms develop or increase

• Do not put this product into the rectum by using fingers or any mechanical device or applicator.

## Drug Facts (continued)

• Remove pubic hair or grossy irritant before using this product because they interfere with the ability of this product to adhere properly to the skin area

If pregnant or breastfeeding, ask a health professional before use

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

### Directions

• Adults: When practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

## Drug Facts (continued)

• For Pruritus Ani: Wait 30 seconds after drying. If the desire to scratch is gone, do not apply cream. If the desire to scratch continues, apply a fingertip amount of ointment to anal and perianal areas. Use finger cot or disposable gloves if desired. Rub or lightly scratch (with fingertips, not fingernails) until the itch is allayed.

• For Anal Fissures: Apply a fingertip amount of cream to the anal area and to the inner rim of the anus.

• Children under 12 years of age: consult a doctor

• Apply externally to the affected area once or twice daily when pain or irritation from anal fissures are present or ideally after bowel movement.

## Drug Facts (continued)

Other information: store at 15-30° C (59-86° F)

### Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cetylal Alcohol, Deionized Water, Dimethicone/Vinyl Dimethicone Crosspolymer, Isopropyl Palmitate, Magnesium Aluminum Silicate, Phenoxethanol, Polyethylene 20, Propylene Glycol, SD Alcohol, Slica, Stearyl Alcohol

Questions or Comments? Call weekdays 9AM to 5 PM CST at 783-517-3419

Manufactured for Pranicura Group LLC by Serris PH, Inc.  
27502 Ted Hunt Rd, Los Fresnos, TX 78566

RES

## PRANICURA 5

glycerin, kaolin, calamine, menthol cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71831-004
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	25.0 g in 100 g
KAOLIN (UNII: 24H4NWX5CO) (KAOLIN - UNII:24H4NWX5CO)	KAOLIN	12.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12.5 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.0 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	

**DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)** (UNII: 9E4CO0W6C5)

**ISOPROPYL PALMITATE** (UNII: 8CRQ2TH63M)

**MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC)

**PHENOXYETHANOL** (UNII: HIE492ZZ3T)

**POLYSORBATE 20** (UNII: 7T1F30V5YH)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**ALCOHOL** (UNII: 3K9958V90M)

**SILICON DIOXIDE** (UNII: ETJ7Z6XBU4)

**STEARYL ALCOHOL** (UNII: 2KR89I4H1Y)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71831-004-01	60 g in 1 JAR; Type 0: Not a Combination Product	10/18/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	10/18/2021	

**Labeler** - Pranicura Products LLC (136154914)

Revised: 11/2025

Pranicura Products LLC