

PRANICURA 5- glycerin, kaolin, calamine, menthol cream
PRANICURA GROUP 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

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

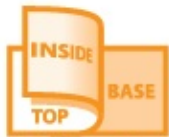
Available only at: www.pranicura.com
Net Wt. 2.1 oz. (60 g)

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

SS

PROOF# **10**

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
Net Wt. 2.1 oz. (40 g)

Drug Facts

Active Ingredients

| | |
|----------------|----------------------|
| Glycerin 20% | Protectant |
| Kaolin 12.5% | Protectant/Anal-Itch |
| Calamine 12.5% | Protectant/Anal-Itch |
| Menthol 1% | Analgesic |

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 alleviated.

• 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, Zinc, 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 GROUP LLC (118320102)