

PLEO NIG- aspergillus niger var. niger solution/ drops
Sanum-Kehlbeck GmbH & Co. KG

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Pleo® Nig
DROPS 5X

Homeopathic Antipruritic Medicine

Indications

For temporary relief of external itching and soreness in the urogenital region.

INGREDIENTS

10 mL Aspergillus niger 5X in a base of purified water.

Tamper Evident

Do not use this product if tamper-evident seal on base of bottle cap is missing or broken.

DOSAGE

5–10 drops, once daily, before mealtime.

WARNING

If symptoms persist more than a few days, contact a licensed practitioner. As with any other drug, if you are pregnant or nursing a baby, seek the advice of a health care professional before using this product.

Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Protect from light and heat.

Made in Germany

Manufactured by:
SANUM-Kehlbeck
GmbH & Co. KG,
Hoya, Germany

Distributed by:
SANUM USA Corp.,
1465 Slater Road,
Ferndale, WA 98248

Rev. 06/2009

PRINCIPAL DISPLAY PANEL - 10 mL Label

Pleo™ Nig DROPS 5X

Homeopathic Antipruritic Medicine

Indications: For temporary relief of external itching and soreness in the urogenital region.

0.34 fl oz (10 mL)

DOSAGE: 5–10 drops, once daily, before mealtime. **WARNING:** If symptoms persist more than a few days, contact a licensed practitioner. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health care professional before using this product.

Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Protect from light and heat. **TAMPER EVIDENT:** Do not use this product if tamper-evident seal on base of bottle cap is missing or broken. **INGREDIENTS:** 10 mL Aspergillus niger 5X in a base of purified water.

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PRINCIPAL DISPLAY PANEL - 10 mL Box

Pleo® Nig
DROPS 5X

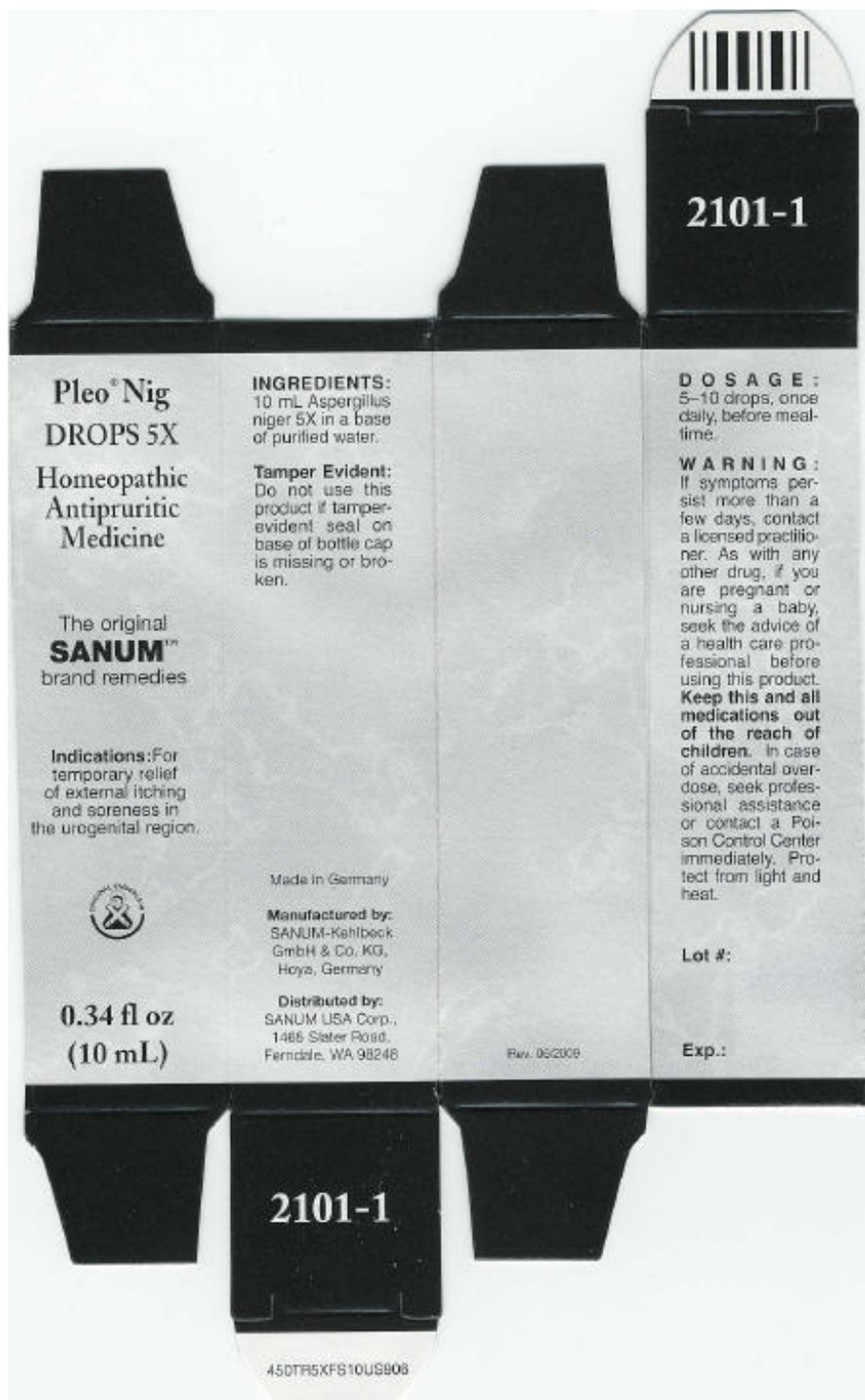
Homeopathic
Antipruritic
Medicine

The original
SANUM™
brand remedies

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ORIGINAL ENDERLEIN

0.34 fl oz
(10 mL)



PLEO NIG

aspergillus niger var. niger solution/ drops

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60681-2101 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|------------------------------|----------------------|--------------------|
| aspergillus niger var. niger (UNII: 9IOA40ANG6) (aspergillus niger var. niger - UNII:9IOA40ANG6) | | aspergillus niger var. niger | 5 [HP_X] in 10 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| water (UNII: 059QF0K00R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:60681-2101-1 | 1 in 1 CARTON | | |
| 1 | | 10 mL in 1 BOTTLE, DROPPER | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| Unapproved homeopathic | | 03/19/1996 | | |

Labeler - Sanum-Kehlbeck GmbH & Co. KG (318386133)

Revised: 9/2009

Sanum-Kehlbeck GmbH & Co. KG