

**CALMS NERVE TENSION SLEEPLESSNESS- passiflora incarnata flower, avena sativa leaf, hops, and chamomile tablet
Hyland's Inc.**

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.

CALMS NERVE TENSION SLEEPLESSNESS

Temporary symptomatic treatment for relief of simple nervous tension & occasional sleeplessness.

HOMEOPATHIC FORMULA

PASSIFLORA 1X Triple Strength HPUS (Passion Flower)

AVENA SATIVA 1X Double Strength HPUS (Oat)

HUMULUS LUPULUS 1X Double Strength HPUS (Hops)

CHAMOMILLA 2X HPUS (Chamomile)

“HPUS” indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Lactose N.F.,
Starch (Corn and Tapioca),
Vegetable Magnesium Stearate.

WARNING

Do not use if imprinted cap band is missing or broken.

If symptoms persist for more than seven days or worsen, consult a Health Care Professional.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Keep this and all medications out of reach of children.

DIRECTIONS

Adults & Children 12 and over:

As a relaxant: Swallow 1-2 tablets with water as needed 3 times daily. For occasional

sleeplessness:

1-3 tablets 1/2 to 1 hour before retiring.

Children 6-12 years:

As a relaxant: 1 tablet with water as needed 3 times daily. For occasional sleeplessness: 1-2 tablets 1 hour before retiring.

QUESTIONS?

CALL US:

(800) 624-9659

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

NDC 54973-1120-3

Hyland's[®]

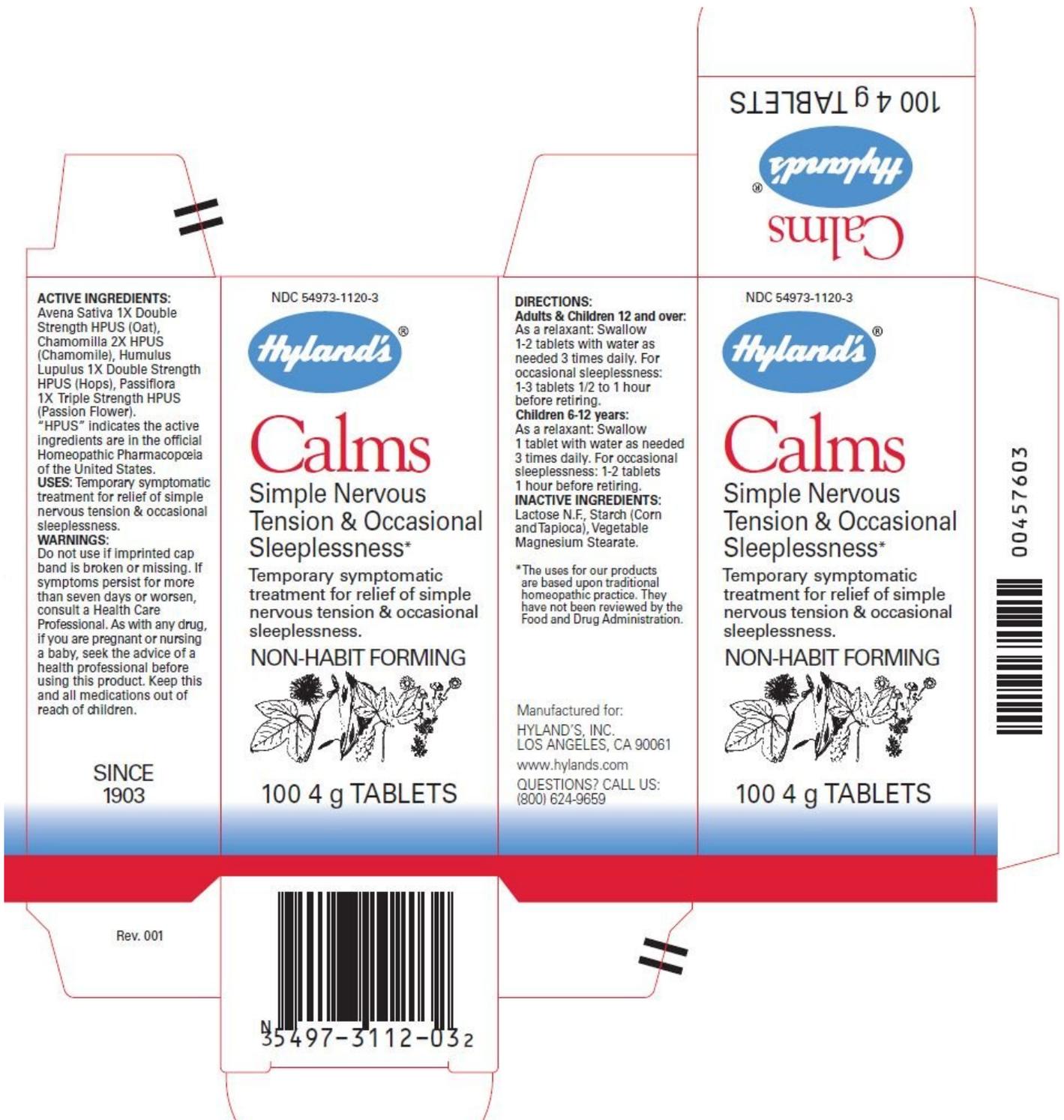
Calms

Simple Nerve Tension
& Occasional Sleeplessness*

Temporary symptomatic
treatment for relief of simple
nervous tension & occasional
sleeplessness.

NON-HABIT FORMING

100 4 g TABLETS



CALMS NERVE TENSION SLEEPLESSNESS

passiflora incarnata flower, avena sativa leaf, hops, and chamomile tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54973-1120 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------|
| PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z) (PASSIFLORA INCARNATA FLOWER - UNII:K8F3G29S6Z) | PASSIFLORA INCARNATA FLOWER | 1 [hp_X] |
| AVENA SATIVA LEAF (UNII: 206PI19V7R) (AVENA SATIVA LEAF - UNII:206PI19V7R) | AVENA SATIVA LEAF | 1 [hp_X] |
| HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83) | HOPS | 1 [hp_X] |
| CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X) | CHAMOMILE | 2 [hp_X] |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LACTOSE (UNII: J2B2A4N98G) | |
| STARCH, TAPIOCA (UNII: 24SC3U704I) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|-------------|---------------------|----------|
| Color | brown (TAN) | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | HYL;CM |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:54973-1120-3 | 1 in 1 CARTON | 01/01/1980 | |
| 1 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 01/01/1980 | |

Labeler - Hyland's Inc. (008316655)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|--|
| Hyland's Inc. | | 008316655 | manufacture(54973-1120) , pack(54973-1120) , label(54973-1120) |