

REAL RELIEF NATURAL WELLNESS CALMING SYRUP- asafoetida, strychnos ignatii seed (ignatia amara), valeriana officinalis whole (valeriana officinalis), oat bran (avena sativa), silver nitrate (argentum nitricum), hyoscyamus niger, paeonia officinalis root (paeonia officinalis), datura stramonium, anamirta cocculus whole (cocculus indicus) liquid Homeolab International (Canada) 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.

Active Ingredients

| | |
|------------------------------------|----------|
| ASAFOETIDA (ASAFETIDA) | 8 [hp-X] |
| IGNATIA AMARA (IGNATUS BEAN) | 8 [hp-X] |
| VALERIANA OFFICINALIS (VALERIAN) | 8 [hp-X] |
| AVENA SATIVA (OAT) | 8 [hp-X] |
| ARGENTUM NITRICUM (SILVER NITRATE) | 8 [hp-X] |
| HYOSCYAMUS NIGER (HENBANE) | 8 [hp-X] |
| PAEONIA OFFICINALIS (PEONY) | 8 [hp-X] |
| STRAMONIUM (THORN APPLE) | 8 [hp-X] |
| ANCOCCULUS INDICUS (INDIAN BERRY) | 8 [hp-X] |

The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Purpose

| | |
|-----------------------|--|
| ASAFOETIDA | Restlessness and Anxiety |
| IGNATIA AMARA | Nervousness |
| VALERIANA OFFICINALIS | Agitation |
| AVENA SATIVA | Sleeplessness |
| ARGENTUM NITRICUM | Nervousness |
| ARGENTUM NITRICUM | Nervousness |
| HYOSCYAMUS NIGER | Anguish and fear |
| PAEONIA OFFICINALIS | Apprehension, anxiety and irritability |
| STRAMONIUM | Nightmares and nervousness |
| COCCULUS INDICUS | Lack of concentration |

Uses

This homeopathic medicine is made from a combination of ingredients traditionally used to help relieve symptoms of*: restlessness, nervousness, irritability, agitation, sleeplessness, lessen nightmares.

*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice, not medical evidence.

Warnings

Stop use and ask a doctor if symptoms worsen:

If you are pregnant or breast feeding, ask a health professional before.

Keep out of reach of children. In case of accidental overdose, contact a medical professional or poison control center immediately.

Directions

- Do not exceed recommended dosage
- Repeat every 6 hours and reduce with improvement or as directed by a health professional.

| Age..... | Dose |
|--------------------------------------|----------------------------|
| Adults and Children 12 + years. | 10 ml or 2 teaspoon (tsp) |
| Children 6 to 11 years of age. | 5 ml or 1 teaspoon (tsp) |
| Children 2 to 5 years of age. | 2.5 ml or ½ teaspoon (tsp) |

Other information

Store at room temperature. • Do not use if seal is broken or missing

*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice, not medical evidence.

Inactive ingredients

Purified water, sorbitol, grape and raspberry flavor, sodium benzoate, potassium sorbate, citric acid.

Product label

Directions: • Do not exceed recommended dosage. • Repeat every 6 hours and reduce with improvement or as directed by a health professional.

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 Adults and Children 12+ years 10 ml or 2 teaspoons (tsp)
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Spanish instructions and warnings on box.
 Instrucciones y advertencias en español en la caja.

Homeopathic Medicine MADE IN CANADA
 MFD for:

 Montreal, QC H4R 1R7 Canada
 1-800-404-4666 / www.homeolab.com

Real Relief
 NATURAL WELLNESS™

CALMING SYRUP

NON-DROWSY FORMULA

Effective relief that helps:

- Great Taste
- Gluten Free
- Alcohol Free
- Sugar Free
- Dye Free

• Restlessness • Nervousness
 • Agitation • Irritability
 • Sleeplessness

SAFE - no side effects, no drug interactions
 HOMEOPATHIC MEDICINE
 MEDICINA HOMEOPÁTICA
 3.4 fl oz (100 mL)

A Natural Solution

NDC: 71971-9042-5

Drug Facts

Active ingredients HPUS: **Purpose**

Asafoetida 8X (Asafoetida) restlessness and anxiety
 Ignatia amara 8X (Ignatius bean) nervousness
 Valeriana officinalis 8X (Valerian) agitation
 Avena sativa 8X (Oats) sleeplessness
 Argentum nitricum 8X (Silver nitrate) nervousness
 Hyoscyamus niger 8X (Henbane) anguish and fear
 Paeonia officinalis 8X (Peony) apprehension, anxiety and irritability
 Stramonium 8X (Thorn apple) nightmares and nervousness
 Cocculus indicus 8X (Indian berry) lack of concentration

The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Uses: This homeopathic medicine is made from a combination of ingredients traditionally used to help symptoms of: • restlessness • nervousness • agitation • irritability • sleeplessness.

Warnings: Stop use and ask a doctor if symptoms get worse.

If you are pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of accidental overdose, contact a medical professional or poison control center immediately.

Datos médicos

Ingredientes activos HPUS* **Objetivo**

Asafoetida 8X (Asafoetida) inquietud y ansiedad
 Ignatia amara 8X (Ignatius bean) nerviosismo
 Valeriana officinalis 8X (Valerian) agitación
 Avena sativa 8X (Oats) insomnio
 Argentum nitricum 8X (Silver nitrate) nerviosismo
 Hyoscyamus niger 8X (Henbane) angustia y miedo
 Paeonia officinalis 8X (Peony) aprensión, ansiedad e irritabilidad
 Stramonium 8X (Thorn apple) pesadillas y nerviosismo
 Cocculus indicus 8X (Indian berry) falta de concentración

*Las letras HPUS significan que los componentes de este producto están oficialmente reconocidos en la Farmacopea Homeopática de los Estados Unidos.

USO: Esta medicina homeopática está compuesta de una combinación de ingredientes tradicionalmente utilizados para aliviar los síntomas de: • inquietud • nerviosismo • agitación • irritabilidad • insomnio.

Advertencia: Deje de usar y consulte a un médico si los síntomas empeoran.

Si está Usted embarazada o si esta amamantando, consulte con un profesional médico antes de utilizar el medicamento.

Mantenga el medicamento fuera del alcance de los niños. En caso accidental de sobredosis, contacte inmediatamente un profesional médico o un centro de toxicología.

Modo de empleo: • No exceder la dosis recomendada • Repita el uso cada 6 horas y reducirlo en caso de mejoría o de una recomendación del médico.

Edad Dosis
 Adultos y niños de 12 años y más 10 ml o 2 cucharaditas de té
 Niños entre 6 y 11 años de edad 5 ml o 1 cucharadita de té
 Niños entre 2 y 5 años de edad 2.5 ml o ½ cucharadita de té

Más información: • No utilizar si falta el precinto en el envase o si este está roto • Guardar el producto a temperatura ambiente.

Ingredientes inactivos: agua purificada, sorbitol, caramelo, benzoato sódico, sorbato potásico, ácido cítrico.

*Estas afirmaciones no han sido examinadas o evaluadas por la "Food and Drug Administration" Están basadas sobre la práctica de la Homeopatía tradicional y no sobre pruebas médicas aceptadas.

Medicina Homeopática elaborada en Canadá
 Fabricada para:

 Montreal, QC H4R 1R7 Canada
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 NATURAL WELLNESS™

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NON-DROWSY FORMULA

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- Restlessness
- Nervousness
- Agitation
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- Sleeplessness

A Natural Solution

• Great Taste
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SAFE - no side effects, no drug interactions
 HOMEOPATHIC MEDICINE
 3.4 fl oz (100 mL)

NDC 71971-9042-5

Real Relief
 NATURAL WELLNESS™

JARABE CALMANTE

FORMULA NO SOÑOLIENTA

Acción rápida-Alivio efectivo que ayuda a:

- Inquietud
- Nerviosismo
- Agitación
- Irritabilidad
- Insomnio

Naturalmente Saludable

• Muy buen sabor
 • Sin gluten
 • Sin alcohol
 • Sin azúcar
 • Sin colorante

Sin peligro alguno-sin efectos secundarios, sin interacción con otros medicamentos
 MEDICINA HOMEOPÁTICA
 3.4 fl oz (100 mL)

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Inactive Ingredients: purified water, sorbitol, grape and raspberry flavor, sodium benzoate, potassium sorbate, citric acid.

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REAL RELIEF NATURAL WELLNESS CALMING SYRUP
 asafoetida, strychnos ignatii seed (ignatia amara), valeriana officinalis whole (valeriana officinalis), oat bran (avena sativa), silver nitrate (argentum nitricum), hyoscyamus niger, paeonia officinalis root (paeonia officinalis), datura stramonium, anamirta cocculus whole (cocculus indicus) liquid

| Product Information | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71971-9042 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|--------------------|
| FERULA ASSA-FOETIDA RESIN (UNII: W9FZA51AS1) (ASAFETIDA - UNII:W9FZA51AS1) | FERULA ASSA-FOETIDA RESIN | 8 [hp_X] in 100 mL |
| STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K) | STRYCHNOS IGNATII SEED | 8 [hp_X] in 100 mL |
| VALERIANA OFFICINALIS WHOLE (UNII: FP6O7F1X9R) (VALERIANA OFFICINALIS WHOLE - UNII:FP6O7F1X9R) | VALERIANA OFFICINALIS WHOLE | 8 [hp_X] in 100 mL |
| OAT BRAN (UNII: KQX236OK4U) (OAT BRAN - UNII:KQX236OK4U) | OAT BRAN | 8 [hp_X] in 100 mL |
| SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A) | SILVER NITRATE | 8 [hp_X] in 100 mL |
| HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3) | HYOSCYAMUS NIGER | 8 [hp_X] in 100 mL |
| PAEONIA OFFICINALIS ROOT (UNII: 8R564U2E1P) (PAEONIA OFFICINALIS ROOT - UNII:8R564U2E1P) | PAEONIA OFFICINALIS ROOT | 8 [hp_X] in 100 mL |
| DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3) | DATURA STRAMONIUM | 8 [hp_X] in 100 mL |
| ANAMIRTA COCCULUS WHOLE (UNII: 8O4P2U3QO2) (ANAMIRTA COCCULUS WHOLE - UNII:8O4P2U3QO2) | ANAMIRTA COCCULUS WHOLE | 8 [hp_X] in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| CARAMEL (UNII: T9D99G2B1R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71971-9042-5 | 1 in 1 CARTON | 09/01/2022 | |
| 1 | | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 09/01/2022 | |

Labeler - Homeolab International (Canada) inc (203639455)