

INSOMNIA RELIEF- passiflora incarnata, valeriana officinalis, avena sativa, cuprum aceticum, hyoscyamus niger pellet
HOMEOLAB USA 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.

DRUG FACTS

ACTIVE INGREDIENTS HPUS

Passiflora incarnata 2X

Valeriana officinalis 2X

Avena sativa 2X

Cuprum aceticum 9X

Hyoscyamus niger 9X

Manufactured according to the Homeopathic Pharmacopoeia of the United States (HPUS)

PURPOSE

Relieves Restlessness, Nervousness and Anxiety Associated with Insomnia

USES

This is a natural Homeopathic remedy that relieves restlessness, nervousness and anxiety associated with insomnia.

WARNINGS

If symptoms persist or worsen, discontinue use and contact a health 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: Allow 3 or 4 pellets to dissolve in mouth one hour before bedtime. Not for use by children.

OTHER INFORMATION

Do not use if cap seal is broken.

Homeolab USA Inc., 3025 De L'Assomption Blvd., Montreal, QC H1N 2H2 Canada

PRODUCT OF CANADA

Package Labeling:





HOMEOPATHIC
MEDICATED
PELLETS

Drug Facts

Active Ingredients HPUS:

Passiflora incarnata (Passion flower) 2X sleeplessness, restlessness
Valeriana officinalis (Valerian) 2X nervousness, sleeplessness
Avena sativa (Oats) 2X nervous exhaustion, cannot sleep
Cuprum aceticum (Crystallized verdigris) 9X sleeplessness
Hyoscyamus niger (Henbane) 9X nervous excitement

Purpose

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

Uses

This is a natural Homeopathic remedy that relieves restlessness, nervousness and anxiety associated with insomnia.*

Warnings

Do not use if cap seal is broken. **Keep this and all medications out of reach of children.** As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. If symptoms persist or worsen, **discontinue use** and contact a health professional.

Directions

Adults: Allow 3 or 4 pellets to dissolve in mouth three times a day. Not for use by children.

Inactive Ingredients

Lactose, saccharose.

*The case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product's efficacy.

RETAIN CARTON
FOR COMPLETE
INSTRUCTIONS

PRODUCT OF CANADA



Mfd for: Homeolab USA, Inc.
3025 de l'Assomption Blvd.,
Montreal, QC H1N 2H2, Canada

1-800-404-4666

HOMEOPATHIC MEDICINE



Rev. 12/19

Insomnia
SYMPTOM RELIEF

80 PELLETS

Insomnia
SYMPTOM RELIEF

HOMEOPATHIC MEDICINE

Fast Acting – Non-Habit Forming

Effective – Pharmacaceutically Formulated
Safe – User-Friendly, Single Dose Dispenser
All-Natural – Non-Toxic, No Side Effects

SATISFACTION GUARANTEED!

HOMEOPATHIC MEDICINE

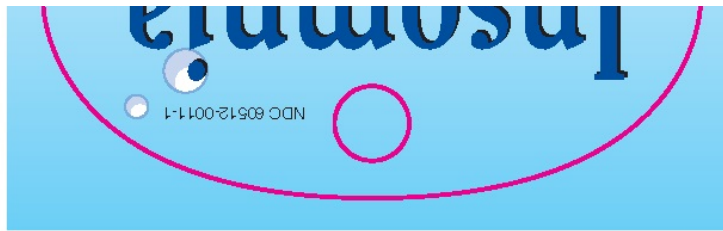


*Relieves Restlessness,
Nervousness and Anxiety
Associated with Insomnia*
All Natural – Safe – Effective
Fast Acting – Non-Habit Forming



SYMPTOM RELIEF

Insomnia



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**HOMEOPATHIC
MEDICATED
PELLETS**

Insomnia

S Y M P T O M R E L I E F

Relieves
Restlessness,
Nervousness
and Anxiety
Associated
with Insomnia.

NDC 60512-0011-1

80 PELLETS

 **HOMEOLAB** USA
The Finest in Homeopathy

Drug Facts

ACTIVE INGREDIENTS HPUS: Passiflora incarnata 2X, Valeriana officinalis 2X, Avena sativa 2X, Cuprum aceticum 9X, Hyoscyamus niger 9X. **WARNINGS:** Do not use if cap seal is broken. Keep out of reach of children. If you are pregnant or nursing a baby, seek the advice of a health professional before using this product. If symptoms persist or worsen, discontinue use and contact a health professional. **DIRECTIONS:** Adults: Allow 3 or 4 pellets to dissolve in mouth one hour before bedtime. Not for use by children. **INACTIVE INGREDIENTS:** Lactose, saccharose. • **PRODUCT OF CANADA.** The case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product's efficacy.

INSOMNIA RELIEF

passiflora incarnata, valeriana officinalis, avena sativa, cuprum aceticum, hyoscyamus niger pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60512-0011
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PASSIFLORA INCARNATA TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA TOP	2 [hp_X]
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	2 [hp_X]
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	2 [hp_X]
CUPRIC ACETATE (UNII: 39M11XPH03) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	9 [hp_X]
HYOSCYAMUS NIGER WHOLE (UNII: 34412PDT5E) (HYOSCYAMUS NIGER WHOLE - UNII:34412PDT5E)	HYOSCYAMUS NIGER WHOLE	9 [hp_X]

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
LACTOSE (UNII: J2B2A4N98G)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	4mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60512-0011-1	80 in 1 TUBE; Type 0: Not a Combination Product	10/18/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/18/2013	

Labeler - HOMEOLAB USA INC. (202032533)

Establishment			
Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC.		202032533	manufacture(60512-0011)