

**SIMPLY DREAMS- *passiflora incarnata*, *valeriana officinalis* tablet**  
**Nartex Laboratorios Homeopaticos, S.A. De C.V.**

*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.*

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**Simply Dreams**

**Active ingredients**

*Passiflora incarnata* 1X HPUS\*

*Valeriana officinalis* 1X HPUS\*

**Purpose**

*Passiflora incarnata* 1X HPUS\*.....Sleeplessness from worries and restlessness

*Valeriana officinalis* 1X HPUS\*.....Restless sleep

\*The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States. "X" is a homeopathic dilution. See [www.nartexlabsusa.com](http://www.nartexlabsusa.com) for more information.

**Uses**

Reduces time to fall asleep if you have difficulty falling asleep. For relief of occasional sleeplessness or intermittent awakening. Helps to reduce difficulty falling asleep. Claims based on traditional homeopathic practice, not accepted medical evidence. These uses have not been evaluated by FDA, and product has not been clinically tested.

**Warnings**

If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.

**Do not use**

- if you have an allergy or hypersensitivity to the components of the formula or have had a prior reaction to this product.
- for children under 12 years of age.

**Stop use and ask a doctor if**

- condition worsens.
- symptoms persist for more than 7 days or clear up and occur again within a few days.
- rash develops.

**If pregnant or breast feeding,** consult 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 and children 12 years and older: take 2 tablets every 24 hours. Dissolves slowly in mouth.
- children under 12 years, do not use.

### **Other information**

- store in a cool and dry place.
- do not use if container seal is broken.

### **Inactive ingredients**

Gelatin, Lactosa USP, Magnesium stearate, Potato starch, Purified water, Sodium benzoate, Talc USP

### **Questions or comments?**

informacion@nartexlabs.com or call 1-877-248-1970 between 9am and 5pm CST. Active ingredients are prepared in accordance with the Homeopathic Pharmacopoeia of the United States, and are therefore non-toxic and have no known side effects.

NDC 34666-402-01

SIMPLY Dreams

Nighttime Sleep Aid

- Helps falling asleep naturally
- No day-time grogginess
- Calms restless sleep

Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated and not clinically tested.

Homeopathic

80 Tablets



**Drug Facts**

**Active Ingredients (in each tablet) Purpose**  
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*Valeriana officinalis* 1X HPUS\* .....Restless sleep  
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**Drug Facts (continued)**

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Product of Mexico  
 Distributed by:  
 Nartex Labs USA, Inc.  
 9543 Bissonnet St. Ste. 302  
 Houston TX 77036 USA  
[www.nartexlabsusa.com](http://www.nartexlabsusa.com)



**Keep box. It contains important information.**

Lot:  
 Exp.:

NDC 34666-402-01

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 80 Tablets



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 \*SEE DIRECTIONS AT THE BACK  
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Non-Drowsy



Non-Habit forming



NDC 34666-402-01

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## SIMPLY DREAMS

passiflora incarnata, valeriana officinalis tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:34666-402
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PASSIFLORA INCARNATA FLOWERING TOP</b> (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	1 [hp_X]
<b>VALERIAN</b> (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X]

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	LogoNartex
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34666-402-01	1 in 1 CARTON	12/03/2021	
1		80 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		12/03/2021	

**Labeler** - Nartex Laboratorios Homeopaticos, S.A. De C.V. (589914576)**Establishment**

Name	Address	ID/FEI	Business Operations
Nartex Laboratorios Homeopaticos, S.A. De C.V.		589914576	manufacture(34666-402)

Revised: 12/2021

Nartex Laboratorios Homeopaticos, S.A. De C.V.