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.

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 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

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Keep box. It contains important information.

Lot: Exp.:

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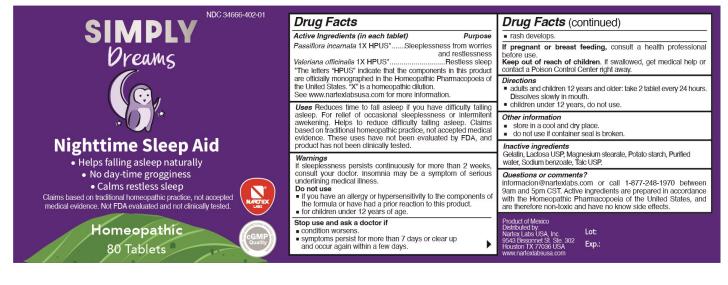


Directions 2 tablets every 24 hours[†] †SEE DIRECTIONS AT THE BACK Claims based on traditional homeopathic practice, not accepted medical evidence. These uses have not been evaluated by FDA, and product has not been clinically tested.

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Non-Drowsy

XA Non-Habit forming



SIMPLY DREAMS passiflora incarnata, valeriana officinalis tablet **Product Information** HUMAN OTC DRUG NDC:34666-402 **Product Type** Item Code (Source) **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA PASSIFLORA INCARNATA 1 [hp X] INCARNATA FLOWERING TOP - UNII:CLF5YFS110) FLOWERING TOP VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII: JWF5YAW3QW) VALERIAN 1 [hp_X] **Inactive Ingredients Ingredient Name** Strength SODIUM BENZOATE (UNII: 0J245FE5EU) GELATIN (UNII: 2G86QN327L) STARCH, POTATO (UNII: 81089SAH3T) TALC (UNII: 7SEV7J4R1U) MAGNESIUM STEARATE (UNII: 70097M6I30) WATER (UNII: 059QF0K00R) LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) **Product Characteristics** Color white Score score with uneven pieces ROUND Size 9mm Shape Flavor **Imprint Code** LogoNartex

Contains

Pa	Packaging							
#	ltem 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				
	approved meopathic		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.