

SLEEP RELIEF

Information for **Health Care Professionals**



SLEEPLESSNESS • RESTLESS SLEEP OCCASIONAL AWAKENING

Sleep disorders encompass more than simple sleeplessness and include: disturbed sleep patterns caused by jet lag or night shifts; frequent awakenings; restless sleep followed by daytime drowsiness; and uneven sleep from worries.¹ At some point we may all experience disruptions in our sleep pattern due to emotional issues.

Conventional over-the-counter sleep aids induce sleep by interfering with the physiological mechanisms of the central nervous system. The most common consequences are residual sedative effects in the morning. Balance, memory, the development of tolerance, as well as the possibility of dependence are also frequent. Herbal and dietary sleep supplements like melatonin have gained widespread use; however, they present their own drug interactions, side effects, and potential for misuse.

SleepCalm®, formulated with plant-based homeopathic ingredients, is used to relieve sleeplessness, restless sleep, and occasional awakening. **It doesn't induce drowsiness, dependence, or tolerance**, and doesn't interact with other drugs or supplements like melatonin.

SleepCalm allows the health care professional to offer a **well-tolerated and melatonin-free solution** to sleep-related disorders, reserving the use of more hazardous drugs for more acute cases. This medicine is available over the counter and health care professionals can also purchase direct from Boiron.


BOIRON®
World Leader in
Homeopathic Medicines
BoironUSA.com/hcp

SLEEP AID²⁻⁴

HOW IT WORKS

ADVANTAGES

SIDE EFFECTS/ DISADVANTAGES

MEDICINES

SleepCalm® Tablets	Homeopathic symptom-specific action on sleep disorders such as sleeplessness, restless sleep, and occasional awakening.	No daytime grogginess, doesn't affect alertness, driving, or operation of machinery; will not mask underlying medical conditions.	Low risk of side effects.
Antihistamines (diphenhydramine, doxylamine)	Sedative — central H1-receptor antagonist.	Quick sedation.	May induce drowsiness, anticholinergic effects, and interactions; usually induces tolerance.
Hypnotic benzodiazepines	Hypnotic action — Gamma amino-butyric acid (GABA) agonists.	Quick and potent action.	May induce drowsiness, affect memory, and coordination; may induce dependence.
Zolpidem	Short term hypnotic action — GABA agonist.	Quick action, effective in inducing sleep.	May induce dizziness, nausea, and nervousness.

SUPPLEMENTS

Melatonin	May interact with GABA neurons, among other possible mechanisms of action.	Used to relieve jet lag or other sleep pattern disturbances.	Avoid in pregnant and nursing women; may induce daytime sleepiness, headaches, dizziness, stomach cramps, and irritability.
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HERBS

Valerian <i>Valeriana officinalis</i>	Sedative — possibly GABA agonist.	Well tolerated at standardized doses, quickly induces a feeling of calm and well-being.	Possibly unsafe (hepatotoxicity); may induce daytime drowsiness; strong odor.
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SleepCalm® is produced by Boiron using the highest standards and quality control processes. The product's active ingredients are manufactured according to the *Homeopathic Pharmacopoeia of the United States*.⁵

Indications for homeopathic medicines have been determined experimentally and verified by years of empirical use by thousands of physicians. Insight into these traditional indications is gained throughout the years as advances are made in the fields of biochemistry and pharmacology. This table shows the relationships between the toxico-pharmacological properties of the strain (in blue) and the general indications of its homeopathic dilution (in purple).^{6,7}

SleepCalm should be used only for its labeled indications.

Black henbane (Solanaceae) <i>Hyoscyamus niger</i>	Nutmeg (Myristicaceae) <i>Myristica fragrans</i>	Passionflower (Passifloraceae) <i>Passiflora incarnata</i>	Thornapple (Solanaceae) <i>Datura stramonium</i>
Hyoscyamine, scopolamine: Restlessness, hallucinations, dilated pupils	Myristicin: Excitation and confusion; hallucinations	Mild sedative action	Atropine, scopolamine, hyoscyamine: Delirium, changes in behavior, photophobia, hyperthermia
Hyoscyamus niger 3C	Nux moschata 4C	Passiflora incarnata 3X	Stramonium 6C
Relieves restless sleep associated with nervousness	Relieves restless sleep	Relieves sleeplessness associated with worries and exhaustion	Relieves sleeplessness with intermittent awakening

+ ADVANTAGES

As a convenient and reliable first choice for restless sleep and sleeplessness, SleepCalm has many advantages:

- No side effects such as daytime grogginess
- No interactions with other medications, herbs, or supplements; can be used in pre-operative protocols or during benzodiazepine withdrawal periods
- Convenient meltaway tablets absorbed sublingually; no food or water needed
- Can be taken on an empty stomach
- Each box contains three sleeves of 20 unflavored tablets

References

1. National Sleep Foundation - Sleep Research & Education. www.sleepfoundation.org. Accessed 2020.
2. Natural Medicines Comprehensive Database. <https://naturalmedicines.therapeuticresearch.com>. Accessed 2020.
3. Martindale W, Reynolds JEF. Martindale: *The Extra Pharmacopoeia*. London: Pharmaceutical Press; 1993.
4. *PDR for Herbal Medicines*. 3rd edition. Thomson PDR
5. *Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry (revised draft)*. U.S. Food and Drug Administration. October 2019. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry>.
6. Demarque D, Jouanny J, Poitevin B, Saint-Jean Y. *Pharmacology and Homeopathic Materia Medica*. 3rd ed. Sainte-Foy-lès-Lyon: CEDH; 2007.
7. Guernonprez M, Pinkas M, Torck M. *Matière Médicale Homéopathique*. 2nd ed. Sainte-Foy-lès-Lyon: Boiron; 1997.





SleepCalm[®]

60 MELTAWAY TABLETS

Drug Facts

Active ingredients** (in each tablet)

Hyoscyamus niger 3C HPUS (0.6 mg) (contains less than 10 ⁻⁹ mg alkaloids)	Relieves restless sleep associated with nervousness
Nux moschata 4C HPUS (0.6 mg)	Relieves restless sleep
Passiflora incarnata 3X HPUS (0.6 mg)	Relieves sleeplessness associated with worries and exhaustion
Stramonium 6X HPUS (0.6 mg) (contains less than 10 ⁻⁸ mg alkaloids)	Relieves sleeplessness with intermittent awakening

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

Purpose*

Uses*

- temporarily relieves: ■ occasional sleeplessness ■ restless sleep ■ intermittent awakening
- helps reduce difficulty falling asleep due to: ■ nervousness ■ worries

Warnings

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Allow 2 tablets to dissolve under the tongue at bedtime.
- Children under 12 years of age: Ask a doctor.

Other information

- do not use if glued carton end flaps are open or if the blister seal is broken
- store below 86°F (30°C)

Inactive ingredients croscarmellose sodium, lactose, magnesium stearate

Questions or comments?

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