

KIDS SLEEP AID

Information for **Health Care Professionals**



SLEEPLESSNESS • RESTLESS SLEEP INTERMITTENT AWAKENING • NIGHTMARES

Good quality sleep is crucial to a child's development and learning. Preschoolers ages 3 to 5 need 10 to 13 hours of sleep, and grade-schoolers ages 6 to 12 require 9 to 12 hours each night. However, the average adolescent in the U.S. is sleep deprived. Two-thirds of children 10 and under and at least 25% under age 5 have parent-reported sleep problems.^{1,2} Additionally, parasomnia (sleepwalking, sleep talking, or crying) occurs in a third of children.³

The causes are multiple: bedtime fears or nightmares, worries, schedule changes, feeling uncomfortable or upset, overexcitement, and time spent looking at digital devices.⁴

Sleep hygiene and adjustments to the sleeping environment are advised but may be difficult for families to follow. As a result, parents often turn to self-medication and use antihistamines, herbs, or supplements that are not risk-free.

Boiron offers a simple solution with **SleepCalm® Kids**, which targets many aspects of sleeplessness commonly affecting children ages 3 and older. It features a range of plant-based and other pure active ingredients that reduce difficulty falling asleep and relieve restless sleep, intermittent awakening, irritability, nightmares, and night terrors. SleepCalm Kids is not a hypnotic and doesn't cause daytime grogginess. This **melatonin-free** children's sleep aid is available over the counter and health professionals can also purchase direct from Boiron.


BOIRON®
World Leader in
Homeopathic Medicines
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SLEEP RELIEF⁵⁻⁸

HOW IT WORKS

ADVANTAGES

SIDE EFFECTS/ DISADVANTAGES

MEDICINES

SleepCalm® Kids Liquid Doses	Provides homeopathic symptom-specific action on symptoms associated with occasional sleeplessness, restless sleep, intermittent awakening, nightmares, and night terrors.	No daytime grogginess; doesn't affect alertness; non-habit forming and no known drug interactions; will not mask symptoms of more serious conditions.	Very 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.

SUPPLEMENTS

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

German chamomile (<i>Matricaria recutita</i>)	Apigenin (an active constituent of the plant) is a possible GABA agonist.	Possibly safe in children when used for short periods (eight weeks).	Possible allergic reactions, including severe hypersensitivity reactions and anaphylaxis.
Lavender oil (<i>Lavandula sp.</i>)	Possible potentiation of GABA neurotransmitter among other possible mechanisms of action.	Possibly safe in adults when used orally for short periods (10 weeks).	Possibly unsafe in children when used topically, particularly on prepubescent boys.
Lemon balm (<i>Melissa officinalis</i>)	Possible interaction with GABAergic neurons among other possible mechanisms of action.	Possibly safe when used orally for up to four months.	Rare occurrences of wheezing and possible increase in appetite.
Passionflower (<i>Passiflora incarnata</i>)	Possible agonist of benzodiazepine receptor.	Possibly safe when used for short periods (one month).	May cause dizziness.
Valerian (<i>Valeriana officinalis</i>)	Sedative — possibly GABA agonist.	Possibly safe in children when taken for short periods of time.	Possibly unsafe (hepatotoxicity); may induce daytime drowsiness; strong odor.



SleepCalm® Kids 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*.⁹

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).^{10,11}

SleepCalm Kids should be used only for its labeled indications.

German chamomile (Asteraceae) <i>Matricaria recutita</i>	Yellow jasmine (Gelsemiaceae) <i>Gelsemium sempervirens</i>	Black henbane (Solanaceae) <i>Hyoscyamus niger</i>
Flavonoids: Anxiolytic (apigenin and luteolin are ligands for the central benzodiazepine receptors); anti-spasmodic effects.	Gelsemine: Headaches, apprehension, diplopia, muscular stiffness, trembling, general sedation.	Atropine, scopolamine, hyoscyamine: Restlessness, hallucinations, dilated pupils.
Chamomilla 9C	Gelsemium sempervirens 9C	Hyoscyamus niger 9C
Relieves restlessness, irritability and crying during sleep.	Relieves sleeplessness due to apprehension.	Relieves irritability and restless sleep associated with nervousness.
Potassium bromide KBr	Passionflower (Passifloraceae) <i>Passiflora incarnata</i>	Thornapple (Solanaceae) <i>Datura stramonium</i>
Low doses: Insomnia with night terrors, restlessness with constant agitation of hands and fingers.	Mild sedative action.	Atropine, scopolamine, hyoscyamine: Delirium, changes in behavior, photophobia, hyperthermia
Kali bromatum 9C	Passiflora incarnata 3C	Stramonium 9C
Relieves irritability and restless sleep with night terrors.	Relieves occasional restless sleep.	Relieves restless sleep with intermittent awakening, nightmares, and night terrors.

+ ADVANTAGES

As a convenient and reliable first choice for occasional sleeplessness, SleepCalm Kids offers many advantages:

- Complete homeopathic formula relieves restless sleep, intermittent awakening, irritability, nightmares, and night terrors associated with upsets, excitement, and schedule changes
- Will not cause residual daytime grogginess
- Easy to administer by squeezing the individual dose into the child's mouth; sublingual absorption leads to quicker general action
- Formulated without melatonin, preservatives, flavors, dyes, lactose, sugar, or artificial sweeteners
- Pre-measured amount allows for hygienic individual use and limits cross-contamination between children
- No known interference with concomitant medications; no contraindications; non-habit forming
- Will not mask symptoms that would lead to the diagnosis of a more serious condition
- Each box contains 15 pre-measured liquid doses

References

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9. *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>.
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SleepCalm[®] Kids

15 PRE-MEASURED LIQUID DOSES

Drug Facts

Active ingredients** (in each 1 mL vial)	Purpose*
Chamomilla 9C HPUS (0.17 mL).....	Relieves restlessness, irritability, and crying during sleep
Gelsemium sempervirens 9C HPUS (0.17 mL)	Relieves sleeplessness (contains less than 10 ⁻¹⁷ mg gelsemine alkaloids) due to apprehension
Hyoscyamus niger 9C HPUS (0.17 mL).....	Relieves irritability and restless sleep (contains less than 10 ⁻¹⁸ mg atropine alkaloids) associated with nervousness
Kali bromatum 9C HPUS (0.17 mL).....	Relieves irritability and (contains less than 10 ⁻¹⁵ mg bromide) restless sleep with night terrors
Passiflora incarnata 3C HPUS (0.17 mL).....	Relieves occasional restless sleep
Stramonium 9C HPUS (0.17 mL)	Relieves restless sleep with (contains less than 10 ⁻¹⁸ mg atropine alkaloids) intermittent awakening, nightmares, and night terrors

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

Uses*

- temporarily relieves symptoms of occasional sleeplessness in children associated with upsets, excitement, and schedule changes such as:
 - restless sleep
 - intermittent awakening
 - irritability
 - nightmares
 - night terrors
- reduces time to fall asleep if your child has difficulty falling asleep

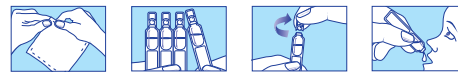
Warnings

- Do not use if** your child has a known allergy to any ingredient in this product.
- Stop use and ask a doctor if** symptoms persist for more than 3 days or worsen. Insomnia may be a symptom of a serious underlying medical illness.
- Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

Children 3 years of age and older: Give 1 dose at bedtime, and again during the night if needed for up to a total of 2 doses per night.



1. Tear open the foil pouch at the notched edge.
2. Snap off one pre-measured dose.
3. Twist to open.
4. Squeeze entire contents into mouth.

Other information

- do not use if glued carton end flaps are open or if inner foil pouch and vials are not intact
- do not refrigerate or freeze
- after opening foil pouch: store unused vials in the foil pouch for no longer than 3 months at a temperature that does not exceed 77°F (25°C)
- after opening the vial: the product must be used immediately
- after administering: discard vial
- do not reuse
- contains 0.0015% alcohol

Inactive ingredients alcohol, purified water

Questions or comments?

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1-800-BOIRON-1 (1-800-264-7661)

ALSO AVAILABLE FROM BOIRON

For Adults & Children
Ages 12 & Over



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