

SLEEP CALM KIDS- matricaria chamomilla whole, gelsemium sempervirens root, hyoscyamus niger, potassium bromide, passiflora incarnata flowering top, datura stramonium liquid
Boiron

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.

SleepCalm Kids

Active ingredients (in each 1 mL vial)**

Chamomilla 9C HPUS (0.17 mL)

Gelsemium sempervirens 9C HPUS (0.17 mL) (contains less than 10^{-17} mg gelsemine alkaloids)

Hyoscyamus niger 9C HPUS (0.17mL) (contains less than 10^{-18} mg atropine alkaloids)

Kali bromatum 9C HPUS (0.17mL) (contains less than 10^{-15} mg bromide)

Passiflora incarnata 3C HPUS (0.17 mL)

Starmonium 9C HPUS (0.17 mL) (contains less than 10^{-18} mg atropine alkaloids)

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

Purpose*

Chamomilla 9C HPUS ... Relieves restlessness, irritability, and crying during sleep

Gelsemium sempervirens 9C HPUS ... Relieves sleeplessness due to apprehension

Hyoscyamus niger 9C HPUS ... Relieves irritability and restless sleep associated with nervousness

Kali bromatum 9C HPUS ... Relieves irritability and restless sleep with night terrors

Passiflora incarnata 3C HPUS ... Relieves occasional restless sleep

Starmonium 9C HPUS ... Relieves restless sleep with intermittent awakening, nightmares and night terrors

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 the time to fall asleep if your child has difficulty falling asleep

Do not use if your child has a known allergy to any ingredient in this product.

Stop and 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.

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.

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

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 the foil pouch: store unused vials in the foil pouch for no longer than 3 months

after opening the vial: the product must be used immediately

after administering: discard vial

do not reuse

contains 0.0015% alcohol

Calms Restless Sleep*

Kids Sleep Aid*

Melatonin Free

15 pre-measured liquid doses

5 pre-measured liquid doses

0.34 fl oz (1 mL) each

99.99% alcohol-free

Fall Asleep, Stay Asleep

*CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.

*C,K,CK, and X are homeopathic dilutions: see BoironUSA.com/info for details.

alcohol, purified water,

BoironUSA.com Info@boiron.com

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

Distributed by Boiron, Inc. Newtown Square, PA 19073

Made in France

Drug Facts

Active ingredients* (in each 1 mL vial)

Chamomilla 9C HPUS (0.17 mL) Relieves restlessness, irritability, and crying during sleep

Gentian semipervinera 9C HPUS (0.17 mL) Relieves sleeplessness due to apprehension (contains less than 10⁻¹ mg gelsemine alkaloids)

Hysopium nigra 9C HPUS (0.17 mL) Relieves irritability and restless sleep associated with nervousness (contains less than 10⁻¹ mg amphetamine alkaloids)

Kali bromatum 9C HPUS (0.17 mL) Relieves irritability and restless sleep with night terrors (contains less than 10⁻¹ mg bromide)

Passiflora incarnata 3C HPUS (0.17 mL) Relieves occasional restless sleep

Strychnos 9C HPUS (0.17 mL) Relieves restless sleep with intermittent awakening, nightmares, and night terrors (contains less than 10⁻¹ mg strychnine alkaloids)

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

Purpose*

temporarily relieves symptoms of occasional sleeplessness in children associated with upset, 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.

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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.

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Drug Facts (continued)

Other information

- do not use if glued carton and 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
- after opening the vial, the product must be used immediately
- after administering: discard vial
- do not reuse
- contains less than 0.0015% alcohol

Inactive ingredients

alcohol, purified water

Questions or comments?

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3 06969 30909 4

NDC 0220-9309-07

MELATONIN-FREE KIDS SLEEP AID*

SleepCalm[®] KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

- Fall Asleep, Stay Asleep
- No Sugar or Artificial Sweeteners



15 DOSES
.034 FL OZ
(1 mL) EACH
99.99%
ALCOHOL-FREE

BOIRON[®]

World Leader in
Homeopathic Medicines

NDC 0220-9309-07

MELATONIN-FREE KIDS SLEEP AID*

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Hysopium nigra 9C HPUS (0.17 mL) Relieves irritability and restless sleep (contains less than 10⁻¹ mg amphetamine alkaloids) associated with nervousness

Kali bromatum 9C HPUS (0.17 mL) Relieves irritability and restless sleep (contains less than 10⁻¹ mg bromide) sleep with night terrors

Passiflora incarnata 3C HPUS (0.17 mL) Relieves occasional restless sleep

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Drug Facts (continued)

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NDC 0220-9309-07

MELATONIN-FREE KIDS SLEEP AID*

SleepCalm[®] KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

- Calms Restless Sleep*
- Fall Asleep, Stay Asleep



5 DOSES
.034 FL OZ
(1 mL) EACH
99.99%
ALCOHOL-FREE

BOIRON[®]

World Leader in
Homeopathic Medicines

Drug Facts

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Chamomilla 9C HPUS (0.17 mL) Relieves restlessness, irritability, and crying during sleep
Gelsemium sempervirens 9C HPUS (0.17 mL) Relieves sleeplessness due to apprehension (contains less than 10⁻⁷ mg gelsemine alkaloids)
Hyscocyamus niger 9C HPUS (0.17 mL) Relieves irritability and restless sleep associated with nervousness
Kali bromatum 9C HPUS (0.17 mL) Relieves irritability and restless sleep with night terrors (contains less than 10⁻⁷ mg bromide)
Passiflora incarnata 3C HPUS (0.17 mL) Relieves occasional restless sleep
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NDC 0220-9309-09

MELATONIN-FREE KIDS SLEEP AID*

SleepCalm® KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

- Fall Asleep, Stay Asleep
- No Sugar or Artificial Sweeteners



15 DOSES
.034 FL OZ
(1 mL) EACH
99.99%
ALCOHOL-FREE

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World Leader in
Homeopathic Medicines

NDC 0220-9309-09

NDC 0220-9309-09

MELATONIN-FREE KIDS SLEEP AID*

Calms Restless Sleep*

SleepCalm® KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

- Fall Asleep, Stay Asleep
- No Next-Day Grogginess



15 DOSES
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Drug Facts (continued)

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- do not use if glued carton and flaps are open or if inner foil pouch and vials are not intact
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- 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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The Boiron Promise

We're committed to your satisfaction. Details at BoironUSA.com/promise.

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Questions or comments?

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

Melatonin-Free

No Preservatives, Flavors, Dyes or Colors, Lactose, Sugar, or Artificial Sweeteners

NDC 0220-9309-09

MELATONIN-FREE KIDS SLEEP AID*

Calms Restless Sleep*

Help Your Body the Natural Way

SleepCalm® KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

SleepCalm® KIDS LIQUID DOSES

HOMEOPATHIC MEDICINE

- Fall Asleep, Stay Asleep
- No Daytime Grogginess

A Better Way

At Boiron, we believe there's a better way to feel better. Since 1932, the Boiron family has been dedicated to providing the purest medicines using sustainable practices. As world leader in homeopathic medicines, quality has always been our passion and your well-being is our goal.

The Boiron Promise

Your health deserves the greatest respect. That's why we're committed to your satisfaction. Please visit BoironUSA.com/promise for details.

Made in France
Distributed by Boiron Inc.,
Newtown Square, PA 19073

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15 Pre-Measured Liquid Doses

BOIRON®
World Leader in
Homeopathic Medicines

99.99%
ALCOHOL-FREE

.034 fl oz
(1 mL) each

matricaria chamomilla whole, gelsemium sempervirens root, hyoscyamus niger, potassium bromide, passiflora incarnata flowering top, datura stramonium liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0220-9309 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------------------|----------|
| DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3) | DATURA STRAMONIUM | 9 [hp_C] |
| POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06) | POTASSIUM BROMIDE | 9 [hp_C] |
| PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O) | PASSIFLORA INCARNATA FLOWERING TOP | 3 [hp_C] |
| MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA WHOLE - UNII:G0R4UBI2ZZ) | MATRICARIA CHAMOMILLA WHOLE | 9 [hp_C] |
| GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q) | GELSEMIUM SEMPERVIRENS ROOT | 9 [hp_C] |
| HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3) | HYOSCYAMUS NIGER | 9 [hp_C] |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0220-9309-09 | 1 in 1 BOX | 09/10/2020 | |
| 1 | | 15 in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:0220-9309-07 | 5 in 1 POUCH; Type 0: Not a Combination Product | 04/26/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 09/10/2020 | |

Labeler - Boiron (282560473)

Registrant - Boiron, Inc. (014892269)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Boiron | | 383674934 | manufacture(0220-9309) |

Revised: 8/2024

Boiron