# SLEEPCALM 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.

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#### 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 <sup>-18</sup> mg atropine alkaloids)

Kali bromatum 9C HPUS (0.17mL) (contains less than 10 <sup>-15</sup> mg bromide)

Passiflora incarnata 3C HPUS (0.17 mL)

Starmonium 9C HPUS (0.17 mL) (contains less than 10 <sup>-18</sup> 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) Chamomila 9C HPUS (0,17 ml) \_\_\_\_\_\_\_Relieves

Purpose ess, imitability. \_\_\_Relieves restlessness, imi and crying during sleep Gelsemium sempervirens 9C HPUS (0,17 ml.) \_\_\_\_\_\_Relieves sibeplessness

Geberarum compervierse 90 FPUS (0,17 ml.) Millions deepleanance in (contain lists mill not firm application disablish) due to supprehension Hyposyamus niger 90 FPUS (0,17 ml.) Pelivines inflability and restlies siper (contains lists than 10°4 mg stropine disablish) associated with nervourses Kall bromatum 90 FPUS (0,17 ml.) Pelivines inflability and restlies (contains lists than 10°4 mg bromate) Releves inflability and restlies (contains lists than 10°4 mg bromate). Releves consistent enables sleep Passificat incommata 30 FPUS (0,17 ml.) Releves consistent enables sleep Stramgnium 9C HPUS (0.17 mt.) Relieves readiese aleep with (contains liess than 10<sup>49</sup> mg atropine alkaloids) intermittent awakening intermittent awakening nightmares, and night terror

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

#### Uses'

USES temporarile relieves symptoms of occasional specifies rese in children associated with upsets, excitement, and schedule changes such as:

| resilies sleep | informational evaluating | infability | informational evaluating | infability | informational evaluation | information | inf

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 liness. Keep out of reach of children. In case of overdose, get medical help or ct 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.











4. Squeeze cetho contents into mouth,

#### Drug Facts (continued)

#### Other information

- onot use if glised carton and flaps are open or if inner to 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
- after administering: clocard via
- osuse for object contains less than 0,0015% alcohol

# Inactive ingredients alcohol, purified water

Questions or comments

# BoirenUSA.com Info@Boiron.com 1-800-80BRON-1 (1-800-264-7661)

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

u, n, ux, and X are homeopathic dilutions: see BoironUSA,com/info for details.



Distributed by Boiron Inc. Newtown Square, PA 19073



#### 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.





#### HOMEOPATHIC MEDICINE

- Calms Restless Sleep\*
- Fall Asleep, Stay Asleep



5 DOSES

.034 FL 0Z (1 mL) EACH

99,99% ALCOHOL-FREE

#### **Drug Facts**

#### Active ingredients" (in each 1 mL vial)

Purpose momilia 9C HPUS (0,17 mL). Relieves restlessness, irritability, and crying during sleep Gelsemium sempervirens 9C HPUS (0.17 mL).... (contains less than 10<sup>47</sup> mg gelsemine alkalloids) ....Relieves sleeplessness due to apprehension

Hyoscyamus niger 9C HPUS (0.17 mL)......(contains less than 10<sup>-18</sup> mg atropine alkaloids) Relieves irritability and restless sleep Kali bromatum 9C HPUS (0.17 mL) ...... (contains less than 10<sup>-15</sup> mg bromide) Passiflora incarnata 3C HPUS (0.17 mL) .... Relieves irritability and restless aleep with night terrors

.. Relieves occasional restless sleer 

The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoele 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

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 liness.

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

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

#### Drug Facts (continued)

#### 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
- a months
  after opening the visit the product must
  be used immediately
  after administering: discard visit
- do not reuse contains 0.0015% alcohol

#### Inactive ingredients

#### **Ouestions or comments?** BoironUSA.com

Info@Boiron.com 1=800=BOIRON=1 (1-800-264-7661)

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## NDC 0220-9309-09 **MELATONIN-FREE** KIDS SLEEP AID



#### HOMEOPATHIC MEDICINE

- Fall Asleep, Stay Asleep
- No Sugar or Artificial



15 DOSES .034 FL 0Z

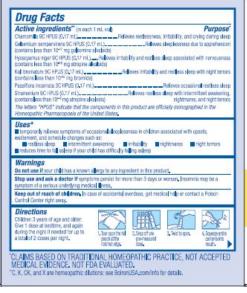
World Leader in **Homeopathic Medicines**  (1 mL) EACH 99.999%

ALCOHOL-FREE















#### 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-beling 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.

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#### SLEEPCALM KIDS

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 |  |  |
| <b>DATURA STRAMONIUM</b> (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: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110) | PASSIFLORA INCARNATA FLOWERING TOP | 3 [hp_C] |  |  |
| MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA WHOLE - UNII:G0R4UBI2ZZ)               | MATRICARIA CHAMOMILLA WHOLE        | 9 [hp_C] |  |  |

|                                                                          | GELSEMIUM<br>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<br>Date | Marketing End<br>Date |
| 1         | NDC:0220-9309-<br>09 | 1 in 1 BOX                                       | 09/10/2020              |                       |
| 1         |                      | 15 in 1 POUCH; Type 0: Not a Combination Product |                         |                       |
| 2         | NDC:0220-9309-<br>07 | 5 in 1 POUCH; Type 0: Not a Combination Product  | 04/26/2023              |                       |

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

# **Labeler -** Boiron (282560473)

# Registrant - Boiron, Inc. (014892269)

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

Revised: 11/2023 Boiron