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.

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

Do not use if your child has a known allergy to any ingredient in this product Stop use and ask a dector if symptoms pensist for more than 3 days or worser. Insomnia may be a symptom of a serious underlying medical illness.

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

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









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

"C, K, CK, and X are homeopathic dilutions: see BolronUSA.com/into for details.

Drug Facts (continued)

Other information

I do not use if allued parton and flags

- Ido not use if gland carton and flaps are open or if inner foll pouch and wisk are not intact ido not retrigerate or treeze rafter opening foll pouch store unused was in the foll pouch for no langer than 2 months.
- 3 months

 after opening the vial the product must be used immediately

 after administering: discard vial
- do not reuse contains 0,0015% alcohol

Inactive ingredients alcohol, purifed water Questions or comments?

Beirant/SA.com Into@Balton.com 1-800-8080H-1 (1-900-264-7661)

> Made in France Distributed by Bairon Inc. lewtown Square, PA 19073





3+ YEARS

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



HOMEOPATHIC MEDICINE

BO RON°

World Leader in

Homeopathic Medicines

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



15 DOSES J034 FL 0Z (1 mL) EACH

99,999% ALCOHOL-FREE

NDC 0220-9309-07

Drug Facts

Active ingredients" (in each 1 mL vial) Purpose' Charcer (is 90 kPUS (0.17 mL) Relieves resilesences, initiability, and crying during alkep

Gelsemium sempervirens 9C HPUS (0,17 ml.) ____ _Relieves sleeplessness contains an armony of the Co. (17 m). Adjaces depotations of the Co. (17 m). Adjaces depotations (by contain lists that 10° mg petermine disablet). As the superhermine hypotypers of the Co. (17 m). Referred inhabitly and restless sleep (contains lists than 10° mg stropine disablet). Referred inhabitly and restless sleep (contains lists than 10° mg bromble). Referred inhabitly and restless (contains lists than 10° mg bromble). Referred inhabitly and restless (contains lists than 10° mg bromble). Referred inhabitly and restless sleep (contains lists than 10° mg bromble). Referred inhabitly and restless sleep (contains lists than 10° mg bromble). Referred inhabitly sleep (contains lists) and contains a contai

Stramonium 9C HPUS (0.17 mt.) Relieves resiless sleep with (contains less than 10⁴⁹ mg atropine alkaloids) intermittent awakening. nightmares, and night ter

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

Uses'

United the Community of the Community of

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, set 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 eethe contents into mouth.

Drug Facts (continued) Other information

- of o not use if glassic carton and flaps are open or if inner toll 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
- then 3 months

 after opening the vial the product
 must be used immediately
 after administering: discard vial
- esuer fon db

contains less than 0,0015% alcohol

Inactive ingredients alcohol, purified water

Questions or comments

BoirenUSA.com Info@Boiron.com 1-800-BOIRON-1 (1-800-264-7861)

'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.



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

World Leader in

Homeopathic Medicines

Calms Restless Sleep*

Fall Asleep, Stay Asleep



5 DOSES .034 FL 0Z (1 mL) EACH

99,99% ALCOHOL-FREE



excitament, and schedule changes such as:

restless sleep intermittent awakening intributery inightmares inight 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 illness.

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.









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

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 3 months
- after opening the vialt the product must
- be used immediately

 after administering: discard vial
- contains 0.0015% alcohol

Inactive ingredients alcohol, purified water

Questions or comments? BoironUSA.com

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

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

nlease recycle







HOMEOPATHIC MEDICINE

Homeopathic Medicines

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



15 DOSES .034 FL 0Z (1 mL) EACH

ALCOHOL-FREE

NDC 0220-9309-09

LIQUID DOSES

(1 mL) EACH

BOIRON* 99,99%

MELATONIN-FREE

KIDS

SLEEP AID

SleepCalm

Fall Asleep, Stay Asleep ■ No Next-Day Grogginess

Drug Facts

es restlessness, irritability, and cryin emium sempervirens 9C HPUS (0.17 mL).... ains less than 10⁴⁷ mg gelsemine alkaloids) ____Relieves sleeples

Relieus irritability and restless slee romatum 9C HPUS (0.17 mL) ... ains less than 10 45 mg bromide

Passiflora incarnata 3C HPUS (0.17 mL)Relieves restless sleep with intermittent awaker nightmares, and night te nots in this product are officially monographed in the

Uses*

Itemporarily releves symptoms of occasional sleeplescenes in children associated with upperts, excitament, and schedule changes such as:

Interest of the procession of the children associated with upperts, excitated by the children associated with upperts and the children associated with upperts and the children associated by the children associ

Warnings
Do not use If your child has a known sllergy to any ingredient in this product,

Step 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 overdose, get medical help or contact a Poison Control Center

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











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

Drug Facts (continued)

- are not intact

 If on or ferfigerabe or freeze

 after opening foil pouch, store unused
 vals in the foil pouch for no binger than
 3 months at a temperature that does not
 second 77°F (25°C)

 after opening the visit the product must
 be used immediately
 after administrating: discard visit
 dit on of resus.
- o not reuse ontains 0.0015% alcohol

Inactive ingredients alcohol, purified water

Questions or comments? BoironUSA.com | Info@Boiron.com 1-800-B0JRON-1 (1-800-264-7661)

The Boiron Promise We're committed to your satisfaction, Details at

BoironUSA.com/promise. Made in France Distributed by Boiron Inc. lewtown Square, PA 19073

ab please recycle



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

Calms Restless Sleep



HOMEOPATHIC MEDICINE

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



World Leader in **Homeopathic Medicines**

MELATONIN-FREE

15 DOSES .034 FL 0Z (1 mL) EACH

99,99% ALCOHOL-FREE

NDC 0220-9309-09

BO RON

A Better Way

At Boiron, we believe there's a better way to feel better. Since 1932, the Boiron family has en dedicated to providing the purest medicines using stainable practices. As world leader in homeopathic medicines, quality has always been our passion and yo 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.

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€5 please recycle

Do not use if your child has a known allergy to any ingredent in this product,

Stop use and ask a doctor if symptoms pensis symptom of a serious underlying medical thess,

sse, get medical help or contact a Pois Keep out at reach of children, in ca Control Center right away.

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













Drug Facts (continued)

Other information

- Smorths at a temperature that does not exceed 77% (26°C) affect operating the visit the product must be used immediately affert administrating; classard visit do not result. contains (0,0019% alloched

Inactive ingredients about

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Melatonin-Free

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



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

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: 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 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)		

P	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			
pplication Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	09/10/2020			
K	•	Citation Date		

Labeler - Boiron (282560473)

Registrant - Boiron, Inc. (014892269)

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

Revised: 8/2024 Boiron