

**SLEEPCALM- matricaria chamomilla whole, gelsemium sempervirens root, hyoscyamus niger, potassium bromide, passiflora incarnata flowering top, datura stramonium pellet
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 Pellet

Active ingredients** (in each pellet)

Chamomilla 9C HPUS (0.07 mg)

Gelsemium sempervirens 9C HPUS (0.07 mg)(contains less than 10^{-21} mg gelsemine)

Hyoscyamus niger 9C HPUS (0.07 mg)(contains less than 10^{-22} mg atropine alkaloids)

Kali bromatum 9C HPUS (0.07 mg)(contains less than 10^{-19} mg bromide)

Passiflora incarnata 3C HPUS (0.07 mg)

Stramonium 9C HPUS (0.07 mg)(contains less than 10^{-21} 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*

Relieves Occasional Sleeplessness, Restless Sleep, Intermittent Awakening, Irritability, and Nightmares

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 ingredients 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 right away.

Directions

- Children 3 years of age or older: Dissolve 5 pellets under the tongue at bedtime, and

again during the night if needed, for up to a total of 2 doses per night.

- Children under 3 years of age: Ask a doctor.

lactose, sucrose

do not use if glued carton end flaps are open or if pellet dispenser seal is broken

contains 0.25 g of sugar per dose

2 PORTABLE TUBES

APPROX. 80 PELLETS EACH

TOTAL 160 PELLETS

Melatonin-Free

Kids Sleep Aid*

Restores a Natural Sleep Pattern

Tubes - contains approx. 80 pellets, 3.8g (0.13 oz)

Turn tube upside down, Twist until 5 pellets are dispensed, Remove cap and pour pellets under the tongue

*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.

BoironUSA.com

Info@Boiron.com

1-800-264-7661

Made in France

Distributed by Boiron Inc.

Newtown Square, PA 19073



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

please recycle



Drug Facts

Active Ingredients*

 (in each pellet)

Chamomilla 9C HPUS (0.07 mg)
Gelsemium sempervirens 9C HPUS (0.07 mg)
(contains less than 10⁻¹¹ mg gelsemine alkaloids)
Hyoscyamus niger 9C HPUS (0.07 mg)
(contains less than 10⁻¹¹ mg atropine alkaloids)
Kali bromatum 9C HPUS (0.07 mg)
(contains less than 10⁻¹¹ mg bromide)
Passiflora incarnata 3C HPUS (0.07 mg)
Stramonium 9C HPUS (0.07 mg)
(contains less than 10⁻¹¹ 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*

Relieves
Occasional
Sleeplessness,
Restless Sleep,
Intermittent
Awakening,
Irritability, and
Nightmares

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 ingredients 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 right away.

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

Drug Facts (continued)

Directions

Children 3 years of age and older:
Dissolve 5 pellets under the tongue at bedtime, and again during the night if needed, for up to a total of 2 doses per night.
Children under 3 years of age:
Ask a doctor.

Other information

do not use if glued carton end flaps are open or if pellet dispenser seal is broken
contains 0.25 g of sugar per dose

Inactive ingredients

lactose, sucrose

Questions or comments?

BoironUSA.com
Info@Boiron.com
1-800-264-7661

NDC 0220-8308-42



MELATONIN-FREE

KIDS SLEEP AID*

Help Your Body
the Natural Way

SleepCalm[®]Kids

MELTAWAY PELLETS

HOMEOPATHIC MEDICINE

Restores a Natural Sleep Pattern

2 PORTABLE TUBES
APPROX. 80 PELLETS EACH
TOTAL 160 PELLETS



BOIRON[®]

World Leader in Homeopathic Medicines

KIDS SLEEP AID NDC 0220-9308-41
 Distributed by Boliron Inc.
 Made in France
SleepCalm^{Kids}
MELTAWAY PELLETS
 1-800-264-7661
 BolironUSA.com

HOMEOPATHIC MEDICINE

Easy Dispensing Tube

Turn tube upside down
 Twist until 5 pellets are dispensed
 Remove cap and pour pellets under the tongue

ETL/HRF

Do not use if pellet dispenser seal is broken.
Peel for Drug Facts and Directions.

Boliron[®] Turn tube upside down & twist cap.
 Contains approx. 80 pellets, 3.8 g (0.13 oz)

Drug Facts

Active ingredients
 Chamomilla 9C HPUS
 Gelsemium sempervirens 9C HPUS
 Hyoscyamus niger 9C HPUS
 Kali bromatum 9C HPUS
 Passiflora incarnata 3C HPUS
 Stramonium 9C HPUS

Purpose
 Relieves Occasional Sleeplessness, Restless Sleep, Intermittent Awakening

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 ingredients in this product.
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Directions
 ■ Children 3 years of age and older: Dissolve 5 pellets under the tongue at bedtime, and again during the night if needed, for up to a total of 2 doses per night.
 ■ Children under 3 years of age: Ask a doctor.

Other information contains 0.25 g of sugar per dose
Inactive ingredients lactose, sucrose

SLEEP CALM

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-9308
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	9 [hp_C]
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	9 [hp_C]
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	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]
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	9 [hp_C]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	white	Score	
Shape	ROUND	Size	4mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9308-42	2 in 1 BOX	05/02/2022	
1	NDC:0220-9308-41	80 in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/02/2022	

Labeler - Boiron (282560473)

Registrant - Boiron, Inc. (014892269)

Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-9308)

