

SLEEP CALM- hyoscyamus niger, nutmeg, passiflora incarnata top, datura stramonium tablet

Laboratoires 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

Active Ingredients** (in each tablet)

Hyoscyamus niger 3C HPUS (0.63 mg) (contains less than 10^{-9} mg alkaloids)

Nux moschata 4C HPUS (0.63 mg)

Passiflora incarnata 3X HPUS (0.63 mg)

Stramonium 6X HPUS (0.63 mg) (contains less than 10^{-8} mg alkaloids)

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

Purpose*

Hyoscyamus niger 3C HPUS (0.63 mg) ... Relieves restless sleep associated with nervousness

Nux moschata 4C HPUS (0.63 mg) ... Relieves restless sleep

Passiflora incarnata 3X HPUS (0.63 mg) ... Relieves sleeplessness associated with worries and exhaustion

Stramonium 6X HPUS (0.63 mg) ... Relieves sleeplessness with intermittent awakening

Uses*

temporarily relieves: occasional sleeplessness, restless sleep, intermittent awakening

helps reduce difficulty falling asleep due to: nervousness, worries

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.

If pregnant or breast-feeding, ask a health professional before use.

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

Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime.

Children under 12 of age: Ask a doctor.

do not use if glued carton end flaps are open or if the blister seal is broken

store below 86 °F (30 °C)

Contains 20 meltaway tablets

Contains 60 meltaway tablets

Contains 120 meltaway tablets

*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.

Calms Restless Mind*

No Known Drug Interactions

Non-habit forming

No artificial sweeteners or flavors

Gluten-free

Melatonin-Free

Sleep Relief*

croscarmellose sodium, lactose, magnesium stearate

BoironUSA.com

Info@boiron.com

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

Made in France

Distributed by Boiron, Inc.

Newtown Square, PA 19073

<p>Drug Facts</p> <p>Active ingredients** (in each tablet)</p> <table border="0"><tr><td>Hyoscyamus niger 3C HPUS (0.63 mg)</td><td>Relieves restless sleep associated with nervousness</td></tr><tr><td>Nux moschata 4C HPUS (0.63 mg)</td><td>Relieves restless sleep</td></tr><tr><td>Passiflora incarnata 3X HPUS (0.63 mg)</td><td>Relieves sleeplessness associated with worries and exhaustion</td></tr><tr><td>Stramonium 6X HPUS (0.63 mg)</td><td>Relieves sleeplessness with intermittent awakening</td></tr></table> <p>The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.</p> <p>Uses*</p> <ul style="list-style-type: none">temporarily relieves:<ul style="list-style-type: none">occasional sleeplessnessrestless sleepintermittent awakeninghelps reduce difficulty falling asleep due to:<ul style="list-style-type: none">nervousnessworries <p>Warnings</p> <p>Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none">Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime.Children under 12 years of age: Ask a doctor. <p>Other information</p> <ul style="list-style-type: none">do not use if glued carton end flaps are open or if the blister seal is brokenstore below 86°F (30°C)	Hyoscyamus niger 3C HPUS (0.63 mg)	Relieves restless sleep associated with nervousness	Nux moschata 4C HPUS (0.63 mg)	Relieves restless sleep	Passiflora incarnata 3X HPUS (0.63 mg)	Relieves sleeplessness associated with worries and exhaustion	Stramonium 6X HPUS (0.63 mg)	Relieves sleeplessness with intermittent awakening	<p>Drug Facts (continued)</p> <p>Inactive Ingredients croscarmellose sodium, lactose, magnesium stearate</p> <p>Questions or comments? BoironUSA.com Info@Boiron.com 1-800-BOIRON-1 (1-800-264-7661)</p> <p>Made in France Distributed by Boiron Inc. Newtown Square, PA 19073</p> <p>please recycle</p> 	<p>NDC 0220-9310-29</p> <p>MELATONIN-FREE SLEEP RELIEF* Fall Asleep, Stay Asleep</p> <p>Help Your Body the Natural Way</p> <p>SleepCalm® MELTAWAY TABLETS</p> <p>HOMEOPATHIC MEDICINE</p> <ul style="list-style-type: none">Calms Restless Mind*No Known Drug Interactions <p>BOIRON® World Leader in Homeopathic Medicines</p> <p>120 MELTAWAY TABLETS Unflavored</p>
Hyoscyamus niger 3C HPUS (0.63 mg)	Relieves restless sleep associated with nervousness									
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SLEEP RELIEF

SleepCalm®

Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime. Children under 12 years of age: Ask a doctor.

BOIRON®

Drug Facts

Active ingredients (in each tablet)

Hyocyamus niger 3C HPUS (0.63 mg) Relieves restless sleep associated with nervousness
Nux moschata 4C HPUS (0.63 mg) Relieves restless sleep associated with nervousness and exhaustion
Passiflora incarnata 3X HPUS (0.63 mg) Relieves sleeplessness associated with worries and exhaustion
Stramonium 6X HPUS (0.63 mg) Relieves sleeplessness with intermittent awakening

Purpose

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

Uses

- temporarily relieves: occasional sleeplessness, restless sleep, intermittent awakening, helps reduce difficulty falling asleep due to: nervousness, worries

Warnings

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime. Children under 12 years of age: Ask a doctor.

Other information

- do not use if glued carton end flaps are open or if the blister seal is broken, store below 86°F (30°C)

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Drug Facts (continued)

Inactive ingredients: croscarmellose sodium, lactose, magnesium stearate

Questions or comments?

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please recycle



NDC 0220-9310-04

MELATONIN-FREE SLEEP RELIEF*

Fall Asleep, Stay Asleep



SleepCalm® MELTAWAY TABLETS

HOMEOPATHIC MEDICINE

- Calms Restless Mind*, No Known Drug Interactions



BOIRON®

World Leader in Homeopathic Medicines

60 MELTAWAY TABLETS Unflavored

SLEEP RELIEF

SleepCalm®

Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime. Children under 12 years of age: Ask a doctor.

BOIRON®

Drug Facts

Active ingredients* (in each tablet)

Hyocyamus niger 3C HPUS (0.63 mg).....Relieves restless sleep associated with nervousness (contains less than 10⁻⁶ mg atropine alkaloids)
Nux moschata 4C HPUS (0.63 mg).....Relieves restless sleep
Passiflora incarnata 3X HPUS (0.63 mg).....Relieves sleeplessness associated with worries and exhaustion

Stramonium 6X HPUS (0.63 mg).....Relieves sleeplessness with intermittent awakening (contains less than 10⁻⁶ mg atropine alkaloids)

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Purpose*

Uses*

- temporarily relieves:
 - occasional sleeplessness
 - restless sleep
 - intermittent awakening
- helps reduce difficulty falling asleep due to:
 - nervousness
 - worries

Warnings

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth at bedtime.
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Other information

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Drug Facts (continued)

Inactive Ingredients
croscarmellose sodium, lactose, magnesium stearate

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19073

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SAMPLE NOT FOR SALE

NDC 0220-9310-91

MELATONIN-FREE SLEEP RELIEF*

Fall Asleep, Stay Asleep

Help Your Body the Natural Way

SleepCalm[®]

MELTAWAY TABLETS

HOMEOPATHIC MEDICINE

- Calms Restless Mind*
- No Known Drug Interactions

BOIRON[®]

World Leader in Homeopathic Medicines

20 MELTAWAY TABLETS
Unflavored

Drug Facts

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Hyocyamus niger 3C HPUS (0.6 mg).....Relieves restless sleep associated with nervousness (contains less than 10⁻⁶ mg alkaloids)
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Purpose*

Uses*

- temporarily relieves:
 - occasional sleeplessness
 - restless sleep
 - intermittent awakening
- helps reduce difficulty falling asleep due to:
 - nervousness
 - worries

Warnings

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness.

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Drug Facts (continued)

Inactive ingredients
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SAMPLE NOT FOR SALE

NDC 0220-9310-91

MELATONIN-FREE SLEEP RELIEF*

Fall Asleep, Stay Asleep Calms Restless Sleep*

Help Your Body the Natural Way

SleepCalm[®]

MELTAWAY TABLETS

HOMEOPATHIC MEDICINE

- Plant-Based Actives
- No Daytime Grogginess

BOIRON[®]

World Leader in Homeopathic Medicines

20 MELTAWAY TABLETS
Unflavored

<p>Drug Facts</p> <p>Active ingredients* (in each tablet) Hyoscyamus niger 3C HPUS (0.6 mg) Relieves restless sleep associated with nervousness (contains less than 10⁻⁴ mg atropine alkaloids) Nux moschata 4C HPUS (0.5 mg) Relieves restless sleep Passiflora incarnata 3X HPUS (0.6 mg) Relieves sleeplessness associated with worries and exhaustion Stramonium 6X HPUS (0.6 mg) Relieves sleeplessness with intermittent awakening (contains less than 10⁻⁴ mg atropine alkaloids) The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.</p> <p>Purpose*</p> <p>temporarily relieves: ■ occasional sleeplessness ■ restless sleep ■ intermittent awakening ■ helps reduce difficulty falling asleep due to: ■ nervousness ■ worries</p> <p>Warnings Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks or worsens. Insomnia may be a symptom of a serious underlying illness. If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ Adults and children 12 years of age and older: Allow 2 tablets to dissolve under the tongue at bedtime. ■ Children under 12 years of age: Ask a doctor.</p> <p>Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■ store below 86°F (30°C)</p> <p><small>*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.</small></p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients croscarmellose sodium, lactose, magnesium stearate</p> <p>Questions or comments? BoironUSA.com Info@Boiron.com 1-800-BOIRON-1 (1-800-264-7661)</p> <p>No Known Drug Interactions</p> <p>No Artificial Colors, Flavors, or Sweeteners</p> <p>Made in France Distributed by Boiron Inc. Newtown Square, PA 19073 please recycle</p> 	<p>MELATONIN-FREE NDC 0220-9310-29</p> <p>SLEEP RELIEF*</p> <p>Fall Asleep, Stay Asleep Calms Restless Sleep</p> <p>Help Your Body the Natural Way</p> <p>SleepCalm™ MELTAWAY TABLETS</p> <p>HOMEOPATHIC MEDICINE</p> <p>■ Plant-Based Actives ■ No Daytime Grogginess</p> <p>BOIRON® World Leader in Homeopathic Medicines</p> <p>120 MELTAWAY TABLETS Unflavored</p>	<p>BOIRON®</p> <p>A Better Way</p> <p>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.</p> <p>The Boiron Promise</p> <p>Your health deserves the greatest respect. That's why we're committed to your satisfaction. Please visit BoironUSA.com/promise for details.</p>
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SLEEP CALM

hyoscyamus niger, nutmeg, passiflora incarnata top, datura stramonium tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-9310
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)		HYOSCYAMUS NIGER	3 [hp_C]
PASSIFLORA INCARNATA TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA TOP - UNII:CLF5YFS110)		PASSIFLORA INCARNATA TOP	3 [hp_X]
DATURA STRAMONIUM (UNII: 6CW4EQ97Z) (DATURA STRAMONIUM			

DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	6 [hp_X]
NUTMEG (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)	NUTMEG	4 [hp_C]

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9310-04	1 in 1 PACKAGE	04/01/2020	
1		60 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0220-9310-29	1 in 1 PACKAGE	12/11/2020	
2		120 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0220-9310-91	1 in 1 PACKAGE	07/12/2021	
3		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/01/2020	

Labeler - Laboratoires Boiron (282560473)

Registrant - Boiron Inc. (014892269)

Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-9310)

