SLEEPCALM- 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 sweetners 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





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,











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,



Drug Facts Active ingredients" (in each tablet) Purpose' Hyoscyamus riger 3C HPUS (0.63 mg).......Releves restless sleep associated with nervousness (contains less than 10⁻⁴ 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 10⁻⁸ mg atropine alkaloids) 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 elegiessness restless elego 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)

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

Drug Facts (continued)

Inactive Ingredients

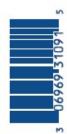
croscarmellose sodium, actose. magnesium stearate

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

Made in France

Distributed by Boiron Inc. Newtown Square, PA





NDC 0220-9310-91 **MELATONIN-FREE** SLEEP RELIEF Fall Asleep, Stay Asleep atura **Sleep**Ca

HOMEOPATHIC MEDICINE

- Calms Restless Mind*
- No Known Drug Interactions



20

World Leader in **Homeopathic Medicines**

Drug Facts

Active ingredients" (in each tablet) Purpose yoscyamus niger 3C HPUS (0.6 mg) . contains less than 10 s mg alkaloids) Relieves restless sleep associated with ner-

Nux moschata 4C HPUS (0.6 mg). Relieves restless sleep

Passiflora incarnata 3X HPUS (0.6 mg)... .Relieves sleeplessness associated with womies and exhaustion Stramonium 6X HPUS (0.6 mg). . Relieves sleeplessness with intermittent awakening

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■ temporarily relieves:

■ ccasional sleeplesaness ■ restless sleep ■ intermittent awakening
■ helps reduce difficulty falling asleep due to: ■ naniousness ■ womles

Stop use and ask a doctor If sleeplessness pensists 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 overdose, get medical help or contact a Poison Control Center right away

- Adults and children 12 years of age and older: Allow 2 tablets to dissolve under the tongue at bertime.
- Children under 12 years of age: Ask a doctor.

Other information

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

CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED, "C, K, CX, and X are homeopathic dilutions: see BottonUSA.com/info for details."

Drug Facts (continued)

Inactive

ingredients

croscarnelises sodium, lactose magnesium stearate

Questions or comments? BoironUSA.com Info@Boiron.com 1-800-B0(RON-1 (1-800-264-7681)

Made in France Distributed by Bairon Inc. Newtown Square, PA

19073







- Plant-Based Actives
- No Daytime Grogginess



20 MELTAWAY TABLETS Unflavored

World Leader in Homeopathic Medicines





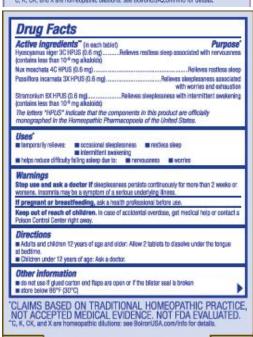




At Boiron, we believe there's a better way to feel better, Since 1932, the Boiron family has been dedicated to providing the purest medicines using sustainable practices. As world leader in homeopathic medicines, quality has always been our passion and your well-being is our goal.

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.







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The Boiron Promise

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MELTAWAY

TABLETS

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

SLEEPCALM

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 CTRANSPILLA (LINII), CCMMFOVOZOV (DATURA CTRANSPILLA			

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)

Revised: 11/2023 Laboratoires Boiron