# SLEEPCALM- hyoscyamus niger, nutmeg, 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.

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## SleepCalm Pellets

# Active ingredients\*\* (in each pellet)

Hyoscyamus niger 3C HPUS (0.11 mg) (contains less than 10 -9 mg atropine alkaloids)

Nux moschata 4C HPUS (0.11 mg)

Passiflora incarnata 3X HPUS (0.11 mg)

Stramonium 6X HPUS (0.11 mg) (contains less than 10 -9 mg atropine alkaloids)

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

Hyoscyamus niger 3C HPUS (0.11 mg) ... Relieves restless sleep associated with nervousness

Nux moschata 4C HPUS (0.11 mg) ... Relieves restless sleep

Passiflora incarnata 3X HPUS  $(0.11 \text{ mg}) \dots$  Relieves sleeplessness associated with worries and exhaustion

Stramonium 6X HPUS (0.11 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.

### **Directions**

- Adults and children 12 years of age and older: Dissolve 5 pellets under the tongue at bedtime.
- Children under 12 years of age: Ask a doctor.

lactose, sucrose

**BoironUSA.com** 

Info@Boiron.Com

1-800-264-7661

Made in France

Distributed by

Boiron, Inc.

Newtown Square, PA 19073

Melatonin-Free

Sleep Relief\*

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

Calms Restless Mind\*

No Known Drug Interactions

**2 PORTABLE TUBES** 

APPROX. 80 PELLETS EACH

**TOTAL 160 PELLETS** 

Tube - Contains approx. 80 pellets, 3.8g, (0.13 oz)

Tube - Do not use if pellet dispenser seal is broken.

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.

# Drug Facts

Active ingredients" (in each pellet) Purpose'

Hypscyamus niger 3C HPUS (0.11 mg) ...... .. Relieves restless sleep (contains less than 10th mg atropine alkalbids) associated with nervousness

Nux moschata 4C HPUS (0,11 mg). .Relieves restless sleep Passiflora incarnata 3X HPUS (0.11 mg)..... ... Relieves sleeplessness associated with womes

and exhaustion Stramonium 6X HPUS (0.11 mg)... ...Ratiowes steeptessness (contains less than 10-9 mg atropine alkalbids) with intermittent awakening

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.

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# Drug Facts

(continued)

#### Directions

Adults and children 12 years of age and older: Dissolve 5 pellets under the tongue at bedtime,

Children under 12 years of age: Ask a doctor,

#### **Other** information

- do not use if glued carton end flans are open or if pellet dispenser seal is broken
- contains 0,25 g of sugar per dose

Inactive ingredients lactose sucmse

Questions or comments? BoironUSA\_com Info@Boiron.com

1-800-264-7661



BOIRON

World Leader in Homeopathic Medicines



Drug Facts Active ingredients Purpose Hyoscyamus niger 3C HPUS... ... Refleves resilless sleep associated with nervousness Nux moschata 4C HPUS... ... Refleves residess sleep Passiflora incamata 3X HPUS..... Relieves steeplassness associated womles and exhaustion Referes speciessness with intermittent swakening Stramonium 6X HPUS .... Uses Intemporarity relieves:
In occasional steeplessness Interfess steep intermittent awakening
helps reduce difficulty falling asleep due to: nervousness worries

Warnings Stop use and ask a doctor if sleeplessness persists way use and ask a doctor if sespessives persess continuously for more than 2 weeks or worsens, Incomnis may be a symptom of a serious underlying lifees.

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

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

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Other Information contains 0,25 g of sugar per dose Inactive ingredients lactose, sucrose



#### 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





# **Drug Facts**

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Refeves sleenlessness Stramonium 6X HPUS (0,11 mg). irisi with intermittent awakening (contains less than 10<sup>-6</sup> mg alkaloids) The letters "HPUS" indicate that the components in this product are officially monographed in the Homaspathic Pharmacoposia of the United States.

#### Uses

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

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#### **Drug Facts** (continued)

#### Directions

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### Other

#### information

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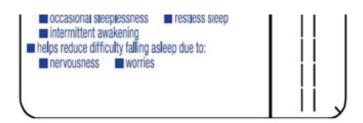
APPROX. 80 PELLETS EACH TOTAL 160 PELLETS

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BOIRONS



### **Drug Facts** Active ingredients Purpose Hyoscyamus niger 3C HPUS......Relieves restless sleep associated with nervousness Nux moschata 4C HPUS......Relieves restless sleep Passiflora incarnata 3X HPUS.......Relieves sleeplessness associated with worries and exhaustion Stramonium 6X HPUS ...... Relieves sleeplessness with intermittent awakening Uses temporarily relieves



### Warnings

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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.

### Directions

- Adults and children 12 years of age and older: Dissolve 5 pellets under the tongue at bedtime.
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Other information contains 0.25 g of sugar per dose Inactive ingredients lactose, sucrose

## **SLEEPCALM**

hyoscyamus niger, nutmeg, passiflora incarnata flowering top, datura stramonium pellet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-9311
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	3 [hp_C]		
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	6 [hp_X]		
PASSIFLORA INCARNATA TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA TOP	3 [hp_X]		
NUTMEG (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)	NUTMEG	4 [hp_C]		

Inactive Ingredients		
Ingredient Name St		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
SUCROSE (UNII: C151H8M554)		

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9311- 42	2 in 1 BOX	04/27/2022	
1	NDC:0220-9311- 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		04/27/2022	

# **Labeler -** Boiron (282560473)

# Registrant - Boiron, Inc. (014892269)

Establishment				
Name	Address	ID/FEI	Business Operations	
Boiron		282560473	manufacture(0220-9311)	

Revised: 4/2024 Boiron