

QUIETUDE- 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.

Quietude

Hyoscyamus niger 3C, Nux moschata 4C, Passiflora incarnata 3X, Stramonium 6X

Temporary relieves occasional sleeplessness and/or restless sleep

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

Adults and children 12 years of age and older: Dissolve 2 tablets in the mouth 3 hours before bedtime. Then, dissolve 2 tablets in the mouth at bedtime.

Children under 12 years of age: Ask a doctor

Croscarmellose sodium, lactose, magnesium stearate

60 tablets

Hyoscyamus niger 3C ... Relieves restless sleep associated with nervousness

Nux moschata 4C... Relieves restless sleep

Passiflora incarnata 3X... Relieves sleeplessness associated with worries and exhaustion.

Stramonium 6X ... Relieves sleeplessness with intermittent awakening.

Store at 68-77 ° F (20-25 ° C)

Questions, Comments

www.boironusa.com

info@boironusa.com

1-800-BOIRON-1

(1-800-264-7661)

Distributed by Boiron Inc.

6 campus boulevard

Newtown Square, PA

19073-3267

Ask doctor before use in children under 12 years of age.

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

Keep out of reach of children

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

Drug Facts

Active ingredients* **Purpose***

Hyoscyamus niger 3C HPUS.....Relieves restless sleep (contains less than 10¹ mg alkaloids per dose) 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 (contains less than 10¹ mg alkaloids per dose) with intermittent awakening

The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.

Uses*

- temporarily relieves occasional sleeplessness and/or restless sleep

Warnings

Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 2 weeks or worsen. 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.

Directions

- Adults and children 12 years of age and older: Dissolve 2 tablets under the tongue 3 hours before bedtime. Then, dissolve 2 tablets under the tongue 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 at 68-77°F (20-25°C)

Inactive ingredients croscarmellose sodium, lactose, magnesium stearate

These "Uses" have not been evaluated by the Food and Drug Administration. *C, K, CK, and X are homeopathic dilutions; see BoironUSA.com/info for details.

SLEEP AID

Quietude®

Drug Facts
(continued)

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Made in France



NDC 0220-9314-04

SLEEP AID*
Sleeplessness • Restless Sleep
Occasional Awakening*

Quietude®

HOMEOPATHIC MEDICINE

- Non-Habit Forming
- No Grogginess
- No Known Drug Interactions

help your body the NATURAL way

BOIRON® 60 QUICK-DISSOLVING TABLETS

World Leader in Homeopathic Medicines

SLEEP AID

Quietude®

The Boiron Promise
At Boiron, we believe there's more than one way to feel better. Since 1932, the Boiron family has been committed to providing quality medicines. As world leader in homeopathy, our passion is your health. Our promise is your satisfaction. Please visit BoironUSA.com/promise for details.

please recycle

Quietude image

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Sleeplessness
Restless Sleep
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HOMEOPATHIC MEDICINE

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- Works Naturally with Your Body

natural ACTIVE INGREDIENTS

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At Boiron, we believe there's a better way to feel good. A better way that works naturally with your body. Since 1932, the Boiron family has been committed to providing safe, natural medicines. As world leader in homeopathic medicines, our passion is your total health. Our promise is your total satisfaction. Please visit boironusa.com/promise for details.

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QUIETUDE			
hyoscyamus niger, nutmeg, passiflora incarnata top, datura stramonium tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-9314
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]	
NUTMEG (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)	NUTMEG	4 [hp_C]	

PASSIFLORA INCARNATA TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA TOP	3 [hp_X]
DATURA STRAMONIUM (UNII: G6W4F0V8Z3) (DATURA STRAMONIUM - UNII:G6W4F0V8Z3)	DATURA STRAMONIUM	6 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9314-04	60 in 1 BOX; Type 0: Not a Combination Product	10/01/2013	10/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/01/2013	10/31/2024

Labeler - Laboratoires Boiron (282560473)

Registrant - Boiron Inc. (014892269)

Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-9314)

Revised: 11/2023

Laboratoires Boiron