

# **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.*

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## **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 100 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

**Drug Facts**

Active ingredients* (in each tablet)	Purpose*
Hyoscyamus niger 3C HPUS (0.63 mg) (contains less than 10 <sup>-4</sup> mg atropine alkaloids)	Relieves restless sleep associated with nervousness
Nuxvomica 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) (contains less than 10 <sup>-4</sup> mg atropine alkaloids)	Relieves sleeplessness 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.

**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 sealed carton end flaps are open or if the blister seal is broken
- store below 86°F (30°C)

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

**Drug Facts (continued)**

**Inactive Ingredients**  
croscarmellose sodium, lactose, magnesium stearate

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

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X004JN7E3B  
New: SleepCalm Tablets 100 Count  
UPC: 308989310922

NDC 0220-9310-92

**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

**100**  
MELTAWAY TABLETS  
Unflavored

NDC 0220-9310-29



# 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

**120**  
MELTAWAY TABLETS  
Unflavored

### Drug Facts

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

Hyoscyamus niger 3C HPUS (0.63 mg) (contains less than 10 <sup>-9</sup> mg atropine alkaloids)	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

#### Purpose\*

Stramonium 6X HPUS (0.63 mg) (contains less than 10 <sup>-9</sup> mg atropine alkaloids)	Relieves sleeplessness with intermittent awakening
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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 and 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?

BoironUSA.com  
Info@Boiron.com  
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Newtown Square, PA 19073

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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®**

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

### Drug Facts

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

Hyoscyamus niger 3C HPUS (0.63 mg) (contains less than 10 <sup>-9</sup> mg atropine alkaloids)	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

#### Purpose\*

Stramonium 6X HPUS (0.63 mg) (contains less than 10 <sup>-9</sup> mg atropine alkaloids)	Relieves sleeplessness 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.

#### 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 and flaps are open or if the blister seal is broken
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### Drug Facts (continued)

#### Inactive ingredients

croscarmellose sodium, lactose, magnesium stearate

#### Questions or comments?

BoironUSA.com  
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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**

<b>Active ingredients*</b> (in each tablet)	<b>Purpose*</b>
Hyoscyamus niger 3C HPUS (0.6 mg) (contains less than 10 <sup>-4</sup> mg alkaloids)	Relieves restless sleep associated with nervousness
Nux moschata 4C HPUS (0.6 mg)	Relieves restless sleep
Passiflora incarnata 3X HPUS (0.6 mg)	Relieves sleeplessness associated with worries and exhaustion
Stramonium 6X HPUS (0.6 mg) (contains less than 10 <sup>-4</sup> mg alkaloids)	Relieves sleeplessness 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 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: Allow 2 tablets to dissolve 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 below 86°F (30°C)

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**Drug Facts (continued)**

**Inactive ingredients**  
 croscarmellose sodium, lactose, magnesium stearate

**Questions or comments?**  
 BoironUSA.com  
 Info@Boiron.com  
 1-800-BOIRON-1  
 (1-800-264-7861)

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**SAMPLE NOT FOR SALE**

NDC 0220-9310-91

**MELATONIN-FREE**  
**SLEEP RELIEF\***

**Fall Asleep, Stay Asleep**  
**Calms Restless Sleep\***



**SleepCalm®**  
**MELTAWAY TABLETS**

**HOMEOPATHIC MEDICINE**

- Plant-Based Actives
- No Daytime Grogginess



**BOIRON®**

**World Leader in Homeopathic Medicines**

**20**  
**MELTAWAY**  
**TABLETS**  
 Unflavored

## Drug Facts

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

*Hyoscyamus niger* 3C HPUS (0.63 mg).....Relieves rest~~less~~ sleep associated with nervousness (contains less than 10<sup>-4</sup> mg atropine alkaloids)  
*Nux moschata* 4C HPUS (0.63 mg).....Relieves rest~~less~~ 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<sup>-4</sup> 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\*

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

## Drug Facts (continued)

**Inactive Ingredients**  
croscarmellose sodium, lactose, magnesium stearate

### Questions or comments?

BoironUSA.com  
Info@Boiron.com  
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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<sup>®</sup>

MELTAWAY TABLETS

HOMEOPATHIC MEDICINE

- Calms Restless Mind\*
- No Known Drug Interactions

BOIRON<sup>®</sup>  
World Leader in  
Homeopathic Medicines

20  
MELTAWAY  
TABLETS  
Unflavored

## Drug Facts

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

*Hyoscyamus niger* 3C HPUS (0.6 mg).....Relieves rest~~less~~ sleep associated with nervousness (contains less than 10<sup>-4</sup> mg atropine alkaloids)  
*Nux moschata* 4C HPUS (0.6 mg).....Relieves rest~~less~~ 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<sup>-4</sup> 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\*

temporarily relieves:

- occasional sleeplessness
- restless sleep
- intermittent awakening

helps reduce difficulty falling asleep due to:

- nervousness
- worries

### 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 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.

### 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.

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

## Drug Facts (continued)

**Inactive ingredients**  
croscarmellose sodium, lactose, magnesium stearate

### Questions or comments?

BoironUSA.com  
Info@Boiron.com  
1-800-BOIRON-1  
(1-800-264-7661)

No Known Drug Interactions  
No Artificial Colors, Flavors, or Sweeteners

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Distributed by Boiron Inc,  
Newtown Square, PA 19073

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NDC 0220-9310-29

# MELATONIN-FREE SLEEP RELIEF\*

## Fall Asleep, Stay Asleep Calms Restless Sleep\*

Help Your Body  
the Natural Way

# SleepCalm<sup>™</sup>

MELTAWAY TABLETS

HOMEOPATHIC MEDICINE

- Plant-Based Actives
- No Daytime Crogginess

BOIRON<sup>®</sup>  
World Leader in  
Homeopathic Medicines

120  
MELTAWAY  
TABLETS  
Unflavored

BOIRON<sup>®</sup>

### A Better Way

At Boiron, we believe there's a better way to feel better. Since 1952, 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.

**Drug Facts**

**Active Ingredients\*** (in each tablet)

Hyoscyamus niger 3C HPUS (0.6 mg).....Relieves restless sleep associated with nervousness (contains less than 10<sup>-6</sup> mg alkaloids)

Nux moschata 4C HPUS (0.6 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<sup>-6</sup> mg alkaloids)

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

**Purpose\***

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 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.

**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.

**Other information**

- do not use if glued carton and 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. T, X, CK, and X are homeopathic dilutions: see BoironUSA.com/info for details.

**Drug Facts** (continued)

**Inactive Ingredients**  
croscarmellose sodium, lactose, magnesium stearate

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

**No Known Drug Interactions**

**No Artificial Colors, Flavors, or Sweeteners**

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NDC 0220-9310-04

**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 Crogginess

**BOIRON®**

World Leader in Homeopathic Medicines

**60 MELTAWAY TABLETS**  
Unflavored

**A Better Way**

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.

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

## SLEEP CALM

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0220-9310
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	

**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		
4	NDC:0220-9310-92	5 in 1 PACKAGE	03/21/2025	
4		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: 3/2025

Laboratoires Boiron