

**SEDALIA- aconitum napellus, belladonna leaf, calendula officinalis flowering top, chelidonium majus, abrus precatorius seed, viburnum opulus root 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.*

-----

**Sedalia**

Aconitum napellus 6C, Belladonna 6C, Calendula officinalis 6C, Chelidonium majus 6C, Jequirity 6C, Viburnum opulus 6C

Aconitum napellus 6C Relieves restlessness, agitation

Belladonna 6C Relieves hypersensitivity to stress

Calendula officinalis 6C Relieves nervous fatigue, hypersensitivity to noise

Chelidonium majus 6C Relieves digestive symptoms caused by stress

Jequirity 6C Relieves uneasiness

Viburnum opulus 6C Relieves nervousness and restless sleep

For temporary relief of nervousness, hypersensitivity and irritability due to stress.

Stop use and ask a doctor if symptoms persist continuously for more than 2 weeks or worsen.

Ask a doctor before use in children younger than 12 years of age.

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): Allow 3 tablets to dissolve in the mouth 3 times a day.

Store at 68-77 ° F (20-25 ° C)

Non habit forming, no drug interactions

Croscarmellose sodium, lactose, magnesium stearate.

Questions, Comments

[www.boironusa.com](http://www.boironusa.com)

[info@boironusa.com](mailto:info@boironusa.com)

1-800-BOIRON-1

(1-800-264-7661)

Boiron Information Center

6 campus Boulevard

Newtown Square, PA

19073-3267

60 tablets

Adult and children 12 years of age and older: dissolve 2 tablets in the mouth 3 times a day.

<p><b>Drug Facts</b></p> <p><b>Active ingredients*</b></p> <p><b>Purpose*</b></p> <p>Aconitum napellus 6C HPUS .....Relieves restlessness, agitation</p> <p>Belladonna 6C HPUS .....Relieves hypersensitivity (contains less than 10<sup>-4</sup> mg alkaloids per dose) to stress</p> <p>Calendula officinalis 6C HPUS .....Relieves nervous fatigue, hypersensitivity to noise</p> <p>Chelidonium majus 6C HPUS .....Relieves digestive symptoms caused by stress</p> <p>Jequirity 6C HPUS .....Relieves uneasiness</p> <p>Viburnum opulus 6C HPUS .....Relieves nervousness and restless sleep</p> <p><i>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</i></p> <p><b>Uses*</b></p> <p>temporarily relieves nervousness, hypersensitivity, irritability, and fatigue due to occasional stress ■ this medicine does not affect alertness</p> <p><b>Warnings</b></p> <p>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. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p><b>Directions</b></p> <p>Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue 3 times a day until symptoms are relieved. Children under 12 years of age: Ask a doctor.</p> <p><b>Other information</b> ■ 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)</p> <p><b>Inactive ingredients</b> croscarmellose sodium, lactose, magnesium stearate</p> <p><small>*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.</small></p>	<p>STRESS RELIEF</p> <p><b>Sedalia</b></p> <p><b>Drug Facts</b> (continued)</p> <p><b>Questions or comments?</b> BoironUSA.com Info@Boiron.com 1-800-BOIRON-1 (1-800-264-7661)</p> <p>Distributed by Boiron Inc. 6 Campus Blvd. Newtown Square, PA 19073-3267</p> <p>Made in France</p>  <p>3 06962 61460 7</p>	<p>NDC 0220-9332-04</p> <p><b>STRESS RELIEF*</b></p> <p>Fatigue • Irritability Nervousness • Hypersensitivity*</p> <p><b>Sedalia</b></p> <p>HOMEOPATHIC MEDICINE</p> <ul style="list-style-type: none"> <li>■ Non-Drowsy</li> <li>■ Non-Habit Forming</li> <li>■ No Known Drug Interactions</li> </ul> <p>help your body the NATURAL way</p> <p><b>BOIRON</b></p> <p>60 QUICK-DISSOLVING TABLETS</p> <p>World Leader in Homeopathic Medicines</p>	<p>STRESS RELIEF</p> <p><b>Sedalia</b></p> <p><b>The Boiron Promise</b></p> <p>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.</p> <p>♻️ please recycle</p>
<p><b>Drug Facts</b></p> <p><b>Active ingredients*</b></p> <p><b>Purpose*</b></p> <p>Aconitum napellus 6C HPUS .....Relieves restlessness, agitation</p> <p>Belladonna 6C HPUS .....Relieves hypersensitivity (contains less than 10<sup>-4</sup> mg alkaloids per dose) to stress</p> <p>Calendula officinalis 6C HPUS .....Relieves nervous fatigue, hypersensitivity to noise</p> <p>Chelidonium majus 6C HPUS .....Relieves digestive symptoms caused by stress</p> <p>Jequirity 6C HPUS .....Relieves uneasiness</p> <p>Viburnum opulus 6C HPUS .....Relieves nervousness and restless sleep</p> <p><i>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</i></p> <p><b>Uses*</b></p> <p>temporarily relieves nervousness, hypersensitivity, irritability and fatigue due to stress ■ this medicine does not affect alertness</p> <p><b>Warnings</b></p> <p>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. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p><b>Directions</b></p> <p>Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue 3 times a day until symptoms are relieved. Children under 12 years of age: Ask a doctor.</p> <p><b>Other information</b> ■ 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)</p> <p><b>Inactive ingredients</b> croscarmellose sodium, lactose, magnesium stearate</p> <p><small>*These "Uses" have not been evaluated by the Food and Drug Administration. *C, K, CK, and X are homeopathic dilutions: see www.boironusa.com for details.</small></p>	<p>STRESS RELIEF</p> <p><b>Sedalia</b></p> <p><b>Drug Facts</b> (continued)</p> <p><b>Questions or comments?</b> www.boironusa.com info@boiron.com 1-800-BOIRON-1 (1-800-264-7661)</p> <p>Distributed by Boiron Inc. 6 Campus Boulevard Newtown Square, PA 19073-3267</p> <p>Made in France</p>  <p>3 06962 61460 7</p>	<p>NDC 0220-9332-04</p> <p><b>STRESS RELIEF*</b></p> <p>Fatigue • Irritability Nervousness Hypersensitivity*</p> <p><b>Sedalia</b></p> <p>HOMEOPATHIC MEDICINE</p> <ul style="list-style-type: none"> <li>■ Non-Drowsy, Non-Habit Forming</li> <li>■ No Drug Interactions</li> <li>■ Works Naturally with Your Body</li> </ul> <p>natural ACTIVE INGREDIENTS</p> <p><b>BOIRON</b></p> <p>60 QUICK-DISSOLVING TABLETS</p> <p>World Leader in Homeopathic Medicines</p>	<p>STRESS RELIEF</p> <p><b>Sedalia</b></p> <p><b>The Boiron Promise</b></p> <p>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.</p> <p>♻️ please recycle</p>

<b>SEDALIA</b>			
aconitum napellus, belladonna leaf, calendula officinalis flowering top, chelidonium majus, abrus precatorius seed, viburnum opulus root tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0220-9332
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	6 [hp_C]

<b>BELLADONNA LEAF</b> (UNII: 6GZW20TIOI) (BELLADONNA LEAF - UNII:6GZW20TIOI)	BELLADONNA LEAF	6 [hp_C]
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	6 [hp_C]
<b>CHELIDONIUM MAJUS</b> (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	6 [hp_C]
<b>ABRUS PRECATORIUS SEED</b> (UNII: 3OM8I6L7CD) (ABRUS PRECATORIUS SEED - UNII:3OM8I6L7CD)	ABRUS PRECATORIUS SEED	6 [hp_C]
<b>VIBURNUM OPULUS BARK</b> (UNII: T1UG6H6805) (VIBURNUM OPULUS BARK - UNII:T1UG6H6805)	VIBURNUM OPULUS BARK	6 [hp_C]

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND (BOIRON)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	;
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9332-04	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/05/1997	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/05/1997	

**Labeler** - Laboratoires Boiron (282560473)

**Registrant** - Boiron Inc. (014892269)

### Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-9332)