

### **17.5 Abnormal Bleeding**

Patients should be cautioned about the concomitant use of Savella and NSAIDs, aspirin, or other drugs that affect coagulation, since the combined use of agents that interfere with serotonin reuptake and these agents has been associated with an increased risk of abnormal bleeding [see *Warnings and Precautions* (5.9)].

### **17.6 Ability to Drive and Use Machinery**

Savella might diminish mental and physical capacities necessary to perform certain tasks such as operating machinery, including motor vehicles. Patients should be cautioned about operating machinery or driving motor vehicles until they are reasonably certain that Savella treatment does not affect their ability to engage in such activities.

### **17.7 Alcohol**

Patients should be advised to avoid consumption of alcohol while taking Savella [see *Warnings and Precautions* (5.6, 5.13)].

### **17.8 Discontinuation**

Patients should be advised that withdrawal symptoms can occur when discontinuing treatment with Savella, particularly when discontinuation is abrupt. [see *Warnings and Precautions* (5.7)]

### **17.9 Pregnancy**

Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during Savella therapy [see *Use in Specific Populations* (8.1)].

### **17.10 Nursing**

Patients should be advised to notify their physician if they are breast-feeding [see *Use in Specific Populations* (8.3)].

### **17.11 FDA-Approved Medication Guide**

#### **MEDICATION GUIDE Savella (Sa-vel-la) Tablets (milnacipran HCl)**

#### **Antidepressant Medicines, Depression and other serious Mental Illnesses, and Suicidal Thoughts or Actions**

Savella is not used to treat depression, but it acts like medicines that are used to treat depression (antidepressants) and other psychiatric disorders.

Read the Medication Guide that comes with you or your family member's antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts or actions with antidepressant medicines. **Talk to your or your family member's healthcare provider about:**

- **all risks and benefits of treatment with antidepressant medicines**
- **all treatment choices for depression or other serious mental illness**

**What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?**

1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of**

**having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.

**3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**

- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

**Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:**

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood
- trouble sleeping (insomnia)

**What else do I need to know about antidepressant medicines?**

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:  
Forest Pharmaceuticals, Inc.  
Manufactured by:  
Forest Laboratories, Inc.

Licensed from Pierre Fabre Medicament and Cypress Bioscience, Inc.

**Revised: December 2009**

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

-----  
NDA-22256

-----  
SUPPL-2

-----  
CYPRESS  
BIOSCIENCE INC

-----  
SAVELLA TABLETS

-----  
**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

LARISSA LAPTEVA  
02/01/2010