



#### Medication Guide

PROZAC® (PRO-zac) (fluoxetine hydrochloride) Pulvule® and Weekly™ Capsule

Read the Medication Guide that comes with PROZAC before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor or pharmacist if there is something you do not understand or you want to learn more about PROZAC.

#### What is the most important information I should know about PROZAC?

Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:

#### 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
- 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
- · trouble sleeping (insomnia)
- · new or worse irritability
- · acting aggressive, being angry, or violent
- · acting on dangerous impulses
- · an extreme increase in activity and talking (mania)
- · or other unusual changes in behavior or mood

# 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.

### What is PROZAC?

## PROZAC is a prescription medicine used:

- for short and long-term treatment of depression in adults and children over the age of 8.
- · for short and long-term treatment of Obsessive Compulsive Disorder (OCD) in adults and children over the age of 7.
- for short and long-term treatment of Bulimia Nervosa in adults.
- · for short-term treatment of Panic Disorder, with or without agoraphobia, in adults.
- with the medicine olanzapine (Zyprexa), for the short-term treatment of episodes of depression that happen with Bipolar I Disorder.
- with the medicine olanzapine (Zyprexa), for the short-term treatment of episodes of depression that do not respond to 2 other medicines, also called treatment resistant depression.

It is not known if PROZAC and olanzapine (Zyprexa) taken together is safe and works in children under 18 years of age.

The symptoms of depression (Major Depressive Disorder, Bipolar I Disorder and Treatment Resistant Depression) include decreased mood, decreased interest, increased guilty feelings, decreased energy, decreased concentration, changes in appetite, and suicidal thoughts or behavior. With treatment, some of your symptoms of depression may improve.

OCD is an anxiety disorder and is characterized by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviors (compulsions). With treatment, some of your symptoms of OCD may improve.

Panic Disorder is an anxiety disorder that includes panic attacks, which are sudden feelings of terror for no reason. You may also have physical symptoms, such as; fast heartbeat, chest pain, breathing difficulty, dizziness. With treatment, some of your symptoms of Panic Disorder may improve.

Bulimia Nervosa, involves periods of overeating followed by purging (e.g. vomiting, excessive laxative use). With treatment, some of your symptoms of Bulimia Nervosa may improve.

If you do not think you are getting better, call your doctor.

Who should not take PROZAC?

# Prescribing Information | Medication Guide

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