

Medication Guide

PROZAC® (PRO-zac)
(fluoxetine hydrochloride)
Pulvule®, Oral Solution, 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
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
- 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?

- Do not take PROZAC if you take a Monoamine Oxidase Inhibitor (MAOI) or if you stopped taking an MAOI in the last **2** weeks.
- Do not take an MAOI **within 5 weeks of stopping PROZAC**. People who take PROZAC close in time to an MAOI can have serious and life-threatening side effects, with symptoms including:
 - high fever
 - continued muscle spasms that you can not control
 - rigid muscles
 - changes in heart rate and blood pressure that happen fast
 - confusion
 - unconsciousness

Ask your doctor or pharmacist if you are not sure if your medicine is an MAOI.
- Do not take PROZAC if you take Mellaril® (thioridazine). Do not take Mellaril **within 5 weeks of stopping PROZAC**. **Mellaril can cause serious heart rhythm problems and you could die suddenly.**
- Do not take PROZAC if you take the antipsychotic medicine pimozide (Orap®).

What should I tell my doctor before taking PROZAC?

PROZAC may not be right for you. Before starting PROZAC, tell your doctor about all your medical conditions, including if you have or had any of the following:

- seizures (convulsions)
- bipolar disorder (mania)
- are pregnant or plan to become pregnant. It is not known if PROZAC will harm your unborn baby.
- are breast-feeding or plan to breast-feed. PROZAC can pass into your breast milk and may harm your baby. You should not breast-feed while taking PROZAC. Talk to your doctor about the best way to feed your baby if you take PROZAC.

Tell your doctor about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. PROZAC and some medicines may interact with each other and may not work as well, or cause possible serious side effects. Your doctor can tell you if it is safe to take PROZAC with your other medicines. Do not start or stop any medicine while taking PROZAC without talking to your doctor first.

If you take PROZAC, you should not take any other medicines that contain fluoxetine hydrochloride:

- Symbiyax
- Sarafem
- Prozac Weekly

You could take too much medicine (overdose).

How should I take PROZAC?

- Take PROZAC exactly as prescribed. Your doctor may need to change (adjust) the dose of PROZAC until it is right for you.
- If you miss a dose of PROZAC, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of PROZAC at the same time.
- **To prevent serious side effects, do not stop taking PROZAC suddenly. If you need to stop taking PROZAC, your doctor can tell you how to safely stop taking it.**
- **If you take too much PROZAC, call your doctor or poison control center right away, or get emergency treatment.**
- PROZAC can be taken with or without food.
- PROZAC is usually taken once a day or once weekly, depending on how your doctor prescribes your medicine.
- If you do not think you are getting better or have any concerns about your condition while taking PROZAC, call your doctor.

What should I avoid while taking PROZAC?

- PROZAC can cause sleepiness and may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how PROZAC affects you.

What are the possible side effects of PROZAC?

PROZAC may be associated with the following serious risks:

- **Serotonin Syndrome:** This is a condition that can be life threatening. Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - agitation
 - hallucinations
 - problems with coordination
 - racing heart beat
 - over-active reflexes
 - fever
 - nausea, vomiting, and diarrhea
- **Severe allergic reactions:** Tell your doctor right away if you get red itchy welts (hives) or, a rash alone or with fever and joint pain, while taking PROZAC. Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - swelling of your face, eyes, or mouth
 - trouble breathing

- **Abnormal bleeding:** Tell your doctor if you notice any increased or unusual bruising or bleeding while taking PROZAC, especially if you take one of these medicines:
 - the blood thinner warfarin (Coumadin, Jantoven)
 - a non-steroidal anti-inflammatory drug (NSAID)
 - aspirin
- **Mania:** You may have a high mood, become extremely irritable, have too much energy, feel pressure to keep talking, or have a decreased need for sleep.
- **Seizures**
- **Loss of appetite**
- **Low salt (sodium) levels in the blood (hyponatremia):** Call your doctor right away if you become severely ill and have some or all of these symptoms:
 - headache
 - feel weak
 - confusion
 - problems concentrating
 - memory problems
 - feel unsteady

Common possible side effects of PROZAC include: abnormal dreams, orgasm problems, decreased appetite, anxiety, weakness, diarrhea, dry mouth, indigestion, flu, difficulty maintaining an erection for sexual activity, trouble sleeping, decreased sex drive, feeling sick to your stomach, nervousness, sore throat, rash, watery nasal discharge, sleepiness, sweating, tremor (shakes), hot flashes, and yawn.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with PROZAC. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROZAC?

- Store PROZAC at room temperature, between 59°F to 86°F (15°C to 30°C).
- Keep PROZAC away from light.
- Keep PROZAC bottle closed tightly.

Keep PROZAC and all medicines out of the reach of children.

General information about PROZAC

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PROZAC for a condition for which it was not prescribed. Do not give PROZAC to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about PROZAC. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about PROZAC that was written for healthcare professionals. For more information about PROZAC call 1-800-Lilly-Rx (1-800-545-5979) or visit www.prozac.com.

What are the ingredients in PROZAC?

Active ingredients: fluoxetine hydrochloride

Inactive ingredients in pulvules: starch, gelatin, silicone, titanium dioxide, iron oxide, and other inactive ingredients. The 10- and 20-mg pulvules also contain FD&C Blue No. 1, and the 40-mg pulvules also contains FD&C Blue No. 1 and FD&C Yellow No. 6.

Inactive ingredients in oral solution: 0.23% alcohol, benzoic acid, flavoring agent, glycerin, purified water, and sucrose.

Inactive ingredients in PROZAC Weekly™ capsules: D&C Yellow No. 10, FD&C Blue No. 2, gelatin, hypromellose, hypromellose acetate succinate, sodium lauryl sulfate, sucrose, sugar spheres, talc, titanium oxide, triethyl citrate, and other inactive ingredients.

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

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