

B2.0NL7104AMP

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 healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

PROZAC and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **PROZAC and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when PROZAC is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping

- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. PROZAC may be associated with these serious side effects:

2. Serotonin Syndrome. This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity
- dizziness
- flushing
- tremor
- seizures

3. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding: PROZAC and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®], Jantoven[®]), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. Seizures or convulsions

6. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

8. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

9. Changes in the electrical activity of your heart (QT prolongation and ventricular arrhythmia including Torsade de Pointes). This condition can be life threatening. The symptoms may include:

- fast, slow, or irregular heartbeat
- shortness of breath
- dizziness or fainting

Do not stop PROZAC without first talking to your healthcare provider. Stopping PROZAC too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is PROZAC?

PROZAC is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

PROZAC is used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Bulimia Nervosa*
- Panic Disorder*
- Depressive episodes associated with Bipolar I Disorder, taken with olanzapine (Zyprexa)
- Treatment Resistant Depression (depression that has not gotten better with at least 2 other treatments), taken with olanzapine (Zyprexa)*

*Not approved for use in children

Talk to your healthcare provider if you do not think that your condition is getting better with PROZAC treatment.

Who should not take PROZAC?

Do not take PROZAC if you:

- are allergic to fluoxetine hydrochloride or any of the ingredients in PROZAC. See the end of this Medication Guide for a complete list of ingredients in PROZAC.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 5 weeks of stopping PROZAC unless directed to do so by your physician.
 - Do not start PROZAC if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take PROZAC close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)
- **take Mellaril[®] (thioridazine). Do not take Mellaril[®] within 5 weeks of stopping PROZAC because this can cause serious heart rhythm problems or sudden death.**
- **take the antipsychotic medicine pimozide (Orap[®]) because this can cause serious heart problems.**

What should I tell my healthcare provider before taking PROZAC? Ask if you are not sure.

Before starting PROZAC, tell your healthcare provider if you:

- Are taking certain drugs or treatments such as:
 - Triptans used to treat migraine headache
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs, MAOIs or antipsychotics
 - Tramadol and fentanyl
 - Over-the-counter supplements such as tryptophan or St. John's Wort
- Electroconvulsive therapy (ECT)
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania

- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- are pregnant or plan to become pregnant. It is not known if PROZAC will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy.
- are breast-feeding or plan to breast-feed. Some PROZAC may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking PROZAC.

Tell your healthcare provider 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, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist 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 healthcare provider first.

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

- | |
|---|
| <ul style="list-style-type: none">• Symbyax• Sarafem• Prozac Weekly |
|---|

How should I take PROZAC?

- Take PROZAC exactly as prescribed. Your healthcare provider may need to change the dose of PROZAC until it is the right dose for you.
- PROZAC may be taken with or without food.
- 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.
- If you take too much PROZAC, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking PROZAC?

PROZAC can cause sleepiness or 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. Do not drink alcohol while using PROZAC.

What are the possible side effects of PROZAC?

PROZAC may cause serious side effects, including:

- See “What is the most important information I should know about PROZAC?”
- **Problems with blood sugar control.** People who have diabetes and take PROZAC may have problems with low blood sugar while taking PROZAC. High blood sugar can happen when PROZAC is stopped. Your healthcare provider may need to change the dose of your diabetes medicines when you start or stop taking PROZAC.
- **Feeling anxious or trouble sleeping**

Common possible side effects in people who take PROZAC include:

- unusual dreams
- sexual problems
- loss of appetite, diarrhea, indigestion, nausea or vomiting, weakness, or dry mouth
- flu symptoms
- feeling tired or fatigued
- change in sleep habits
- yawning
- sinus infection or sore throat
- tremor or shaking
- sweating
- feeling anxious or nervous
- hot flashes
- rash

Other side effects in children and adolescents include:

- increased thirst
- abnormal increase in muscle movement or agitation
- nose bleed
- urinating more often
- heavy menstrual periods
- possible slowed growth rate and weight change. Your child’s height and weight should be monitored during treatment with PROZAC.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of PROZAC. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store PROZAC?

- Store PROZAC at room temperature between 59°F and 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 healthcare provider. You may ask your healthcare provider or pharmacist for information about PROZAC that is written for healthcare professionals.

For more information about PROZAC call 1-800-Lilly-Rx (1-800-545-5979).

What are the ingredients in PROZAC?

Active ingredient: fluoxetine hydrochloride

Inactive ingredients:

- **PROZAC 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.
- **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.

Medication Guide revised Month dd, yyyy

**Marketed by: Lilly USA, LLC
Indianapolis, IN 46285, USA**

Copyright © 2009, yyyy, Eli Lilly and Company. All rights reserved.

B3.0NL7104AMP