

ZYPREXA is approved for the treatment of schizophrenia, for acute manic or mixed episodes of bipolar disorder, and for maintenance treatment in bipolar disorder. Efficacy was established in three clinical trials in adult patients with schizophrenia: two 6-week trials and one maintenance trial; and in three clinical trials in adult patients with manic or mixed episodes of bipolar I disorder: two 3-4 week trials and one maintenance trial.

For a list of symptoms and complete diagnostic criteria for schizophrenia and for manic/mixed episodes of bipolar I disorder, see the *Diagnostic and Statistical Manual of Mental Disorders*, Ed 4, Text Revision (American Psychiatric Association; 2000).



Information for Physicians and Healthcare Professionals

[ZYPREXA Prescribing Information](#) | [Important Safety Information and Boxed Warnings](#)
[ZYPREXA Medication Guide](#)

[ZYPREXA+Fluoxetine Prescribing Information](#) | [ZYPREXA+Fluoxetine Medication Guide](#)

 

Captured 7/13/11

Important Safety Information about ZYPREXA® (olanzapine) and ZYPREXA + fluoxetine HCl combination

Please read the Medication Guides that come with ZYPREXA and fluoxetine HCl before you start taking them and each time you get a refill

What are the possible side effects of ZYPREXA and ZYPREXA + fluoxetine combination?

ZYPREXA and ZYPREXA + fluoxetine combination are associated with possible side effects. Tell your doctor about any side effect that concerns you.

Serious side effects may happen when you take ZYPREXA or ZYPREXA + fluoxetine combination, including:

- Increased risk of death in elderly patients with dementia-related psychosis:** Medicines like ZYPREXA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ZYPREXA is not approved for treating psychosis in the elderly with dementia.
- Antidepressants can increase suicidal thoughts and behaviors in children, teens, and young adults.** Suicide is a known risk of depression and some other psychiatric disorders. Call your doctor right away if you have new or worsening depression symptoms, unusual changes in behavior, or thoughts of suicide. Be especially observant within the first few months of treatment or after a change in dose.

ZYPREXA + fluoxetine combination is not approved for children and adolescents.

- **Suicidal thoughts or actions.** Persons taking ZYPREXA + fluoxetine combination may be more likely to think about killing themselves or actually try to do so, especially when treatment is first started or the dose is changed. People close to patients taking ZYPREXA + fluoxetine combination can help by paying attention to changes in patient's mood or actions. Contact the doctor right away if someone using ZYPREXA + fluoxetine combination talks about or shows signs of killing him or herself or has sudden changes in mood, behaviors, thoughts, or feelings. If you are taking ZYPREXA + fluoxetine combination yourself and you start having any of these symptoms, tell your doctor about this right away.
- **Suicide.** The symptoms of bipolar I disorder, treatment resistant depression, or schizophrenia may include **thoughts of suicide** or of hurting yourself or others. If you have these thoughts at any time, tell your doctor or go to an emergency room right away.
- **High blood sugar (hyperglycemia).** High blood sugar can happen if you have diabetes already or even if you have never had diabetes. In rare cases, this could lead to ketoacidosis (build up of acid in the blood due to ketones), coma, or death. Your doctor should do lab tests to check your blood sugar before you start taking ZYPREXA and during treatment. In people who do not have diabetes, sometimes high blood sugar goes away when ZYPREXA is stopped. People with diabetes and some people who did not have diabetes before taking ZYPREXA need to take medicine for high blood sugar even after they stop taking ZYPREXA. If you have diabetes, follow your doctor's instructions about how often to check your blood sugar while taking ZYPREXA.

Call your doctor if you have any of these symptoms of high blood sugar (hyperglycemia) while taking ZYPREXA:

- feel very thirsty
- need to urinate more than usual
- feel very hungry
- feel weak or tired
- feel sick to your stomach
- feel confused, or your breath smells fruity
- **High cholesterol and triglyceride levels in the blood (fat in the blood).** This may happen in people treated with ZYPREXA, especially in teenagers (13-17 years old). You may not have any symptoms, so your doctor should do blood tests to check your cholesterol and triglyceride levels before you start taking ZYPREXA and during treatment.
- **Increase in weight (weight gain).** Weight gain is very common in people who take ZYPREXA. Teenagers (13-17 years old) are more likely to gain weight and to gain more weight than adults. Some people may gain a lot of weight while taking ZYPREXA, so your doctor should check your weight regularly. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet, and exercising.
- **Increased risk in teenagers (13-17 years old):** Possible serious risks of weight gain and increases in cholesterol and triglycerides are more common in teenagers than in adults. You and your doctor should decide if other available treatments should be used first. Before your teenager takes ZYPREXA, talk with your doctor about the possible long-term risks of teenagers taking ZYPREXA.
- **Strokes and "mini-strokes" called transient ischemic attacks (TIAs).** These are more common in elderly people with dementia-related psychosis (elderly people who have lost touch with reality due to confusion and memory loss). ZYPREXA is not approved for these patients.
- **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 ZYPREXA + fluoxetine combination. Call your doctor right away if you become severely ill and have swelling of your face, eyes or mouth, and/or trouble breathing.
- **Neuroleptic malignant syndrome (NMS).** NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including ZYPREXA. NMS can cause death and must be treated in a hospital. The symptoms include high fever; excessive sweating; rigid muscles; confusion; and changes in breathing, heartbeat, and blood pressure. Call your doctor right away if you become severely ill and have any of these symptoms.
- **Tardive dyskinesia.** This condition causes body movements that keep happening and that you cannot control. These movements usually affect the face and tongue. Tardive dyskinesia may not go away, even if you stop taking ZYPREXA. It may also start after you stop taking ZYPREXA. Tell your doctor if you get any body movements that you cannot control.
- **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 while taking ZYPREXA + fluoxetine combination: agitation; hallucinations; problems with coordination; racing heart beat; over-active reflexes; fever; nausea, vomiting, and diarrhea.
- **Abnormal bleeding.** Tell your doctor if you notice any increased or unusual bruising or bleeding while taking ZYPREXA + fluoxetine combination, especially if you take one of these medications: the blood thinner warfarin (Coumadin, Jantoven), a nonsteroidal anti-inflammatory drug (NSAID), aspirin.
- **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 while taking ZYPREXA + fluoxetine combination: headache, feel weak, confusion, problems concentrating, memory problems, feel unsteady.
- **Decreased blood pressure when you change position,** with symptoms of dizziness, fast or slow heart beat, or fainting.

- **Decreases in white blood cells** (infection fighting cells) have been reported in some patients taking antipsychotic agents, including ZYPREXA. Patients with a history of a significant decrease in white blood cell (WBC) count or who have experienced a low WBC count due to drug therapy should have their blood tested and monitored during the first few months of therapy.
- **Trouble swallowing**, that can cause food or liquid to get into your lungs.
- **Seizures**. Tell your doctor if you have a seizure during treatment with ZYPREXA.
- **Problems with control of body temperature**. You could become very hot, for instance when you exercise a lot or stay in an area that is very hot. It is important for you to drink water to avoid dehydration. Call your doctor right away if you become severely ill and have some or all of these symptoms of dehydration: sweating too much or not at all, dry mouth, feeling very hot, feeling thirsty, not able to produce urine.
- **Increases in prolactin** (a naturally occurring hormone in the body) have been reported in some patients taking ZYPREXA and other medications like it, and these increases can continue while taking the medication. Some patients who have taken medications that increase prolactin have reported milk production from the breasts, stopping of menstrual periods, enlargement of the breasts in men, and impotence
- **ZYPREXA 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 ZYPREXA affects you.

Who should not take ZYPREXA + fluoxetine combination?

- Do not take ZYPREXA + fluoxetine combination if you already 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 ZYPREXA + fluoxetine combination. People who take ZYPREXA + fluoxetine combination close in time to an MAOI can have serious and life-threatening side effects, with symptoms including: high fever, continued muscle spasms that you cannot 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 ZYPREXA + fluoxetine combination if you already take Mellaril (thioridazine) or within 5 weeks of stopping ZYPREXA + fluoxetine combination. Mellaril can cause serious heart rhythm problems and you could die suddenly.
- Do not take ZYPREXA + fluoxetine combination if you take the antipsychotic medicine pimozide (Orap).

Common possible side effects of ZYPREXA include:

- Sleepiness
- Lack of energy
- Dry mouth
- Increased appetite
- Changes in behavior
- Restlessness
- Dizziness
- Tremors (shakes)
- Having hard or infrequent stools

Other common possible side effects in teenagers (13-17 years old) include: headache, stomach-area (abdominal) pain, pain in your arms or legs, or tiredness. Teenagers experienced greater increases in prolactin, liver enzymes, and sleepiness, as compared with adults.

Common possible side effects of ZYPREXA + fluoxetine combination include:

- Tiredness
- Sleeping for long periods of time
- Dry mouth
- Feeling weak
- Blurred vision
- Swelling of your hands and feet
- Increased appetite
- Tremors (shakes)

This is not a complete list of possible side effects. If you have questions or if you have any side effects that concern you, talk with your doctor and/or pharmacist.

Other important safety information

Tell your doctor if you are taking, or plan to take, any prescription or over-the-counter drugs including vitamins and herbal supplements. ZYPREXA and some medicines may interact with each other and may not work as well, or cause possible serious side effects. Do not start or stop any medicine while taking ZYPREXA without talking to your doctor first.

ZYPREXA may not be right for you. Before starting ZYPREXA or ZYPREXA + fluoxetine combination, tell your doctor if you have or had: heart problems, seizures, diabetes or high blood sugar levels (hyperglycemia), high cholesterol or triglyceride levels in your blood, liver problems, low or high blood pressure, strokes or "mini-strokes" also called transient ischemic attacks (TIAs), bleeding problems, Alzheimer's disease, narrow-angle glaucoma, enlarged prostate in men, bowel obstruction, phenylketonuria (because ZYPREXA ZYDIS contains phenylalanine), breast cancer, thoughts of suicide or hurting yourself, or any other medical condition. Also tell your doctor if you are pregnant or plan to become pregnant (it is not known if ZYPREXA will harm your unborn baby), or if you are breast-feeding or plan to breast-feed (ZYPREXA can pass into your breast milk and may harm your baby. You should not breast-feed while taking ZYPREXA. Talk to your doctor about the best way to feed your baby if you take ZYPREXA).

Tell your doctor if you exercise a lot or are in hot places often.

If you take ZYPREXA + fluoxetine combination, you should not take any other medicines that contain fluoxetine hydrochloride (Prozac, Prozac Weekly, Symbyax or Sarafem). You could take too much medicine.

Take ZYPREXA exactly as prescribed. To prevent serious side effects, do not stop taking ZYPREXA suddenly. If you need to stop taking ZYPREXA, your doctor can tell you how to safely stop taking it.

Avoid the use of alcohol while taking ZYPREXA.

ZYPREXA has been approved for use in adolescents (13-17 years old) to treat schizophrenia and manic or mixed episodes that happen with bipolar I disorder. ZYPREXA has not been approved for use in children under 13 years of age.

It is not known if ZYPREXA + fluoxetine combination is safe and works in children under 18 years of age.

If you have any questions or concerns, or if you want to report any problems with the use of ZYPREXA, contact your doctor, pharmacist, or other healthcare provider. For more information, talk with your doctor or visit www.ZYPREXA.com or call 1-800-LillyRx.

For complete safety profile, see the [full Prescribing Information for ZYPREXA](#) and the [full Prescribing Information for ZYPREXA + Fluoxetine](#), along with the [ZYPREXA Medication Guide](#) and [ZYPREXA+Fluoxetine Medication Guide](#).

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