

**CONSENT TO TREATMENT WITH ZYPREXA  
AND IMPORTANT INSTRUCTIONS**

Patient Name: \_\_\_\_\_ Age: \_\_\_\_\_

The following information is being provided to help you decide whether to take the drug Zyprexa as prescribed by your doctor. Your doctor has prescribed Zyprexa, but the decision whether or not to take it is yours alone. In deciding whether to take a medicine, the risks of taking the medicine must be weighed against the good it will do. In recommending Zyprexa, your doctor has considered, among other things, the risks and benefits of: (1) treatment with Zyprexa (2) alternatives to Zyprexa and (3) no treatment. You should consider these things, as well.

**QUESTIONS ENCOURAGED**

Please feel free to ask your doctor, nurse or other staff any questions you may have about your treatment, your condition, Zyprexa and this form. We will answer any questions and we will give you a copy of this form. We are also available to any questions that come up as your treatment continues.

**DRUG NAME AND CLASS**

Your doctor has prescribed Zyprexa, a drug manufactured by Ely Lilly and Company. “zyprexa” is a brand name. The scientific name for Zyprexa is “olanzapine.” Zyprexa is one drug in a category or class of drugs called “atypical antipsychotics”. This class of drugs is also sometimes referred to as “second generation antipsychotics.”

**USAGE**

Zyprexa taken by mouth is used for treatment of (1) schizophrenia and (2) acute mixed or manic episodes associated with bipolar I disorder. A combination of Zyprexa taken by mouth and lithium or valproate is used for short term treatment of acute manic episodes associated with bipolar I disorder. Zyprexa taken intramuscularly (by an injection) is used for treatment of agitation associated with schizophrenia and bipolar I mania.

As with all medicines, when Zyprexa is prescribed for extended periods of time, its usefulness should be reevaluated from time to time.

**OFF LABEL USES**

The uses for Zyprexa noted above are described in a paper that the manufacturer distributes with Zyprexa to inform doctors and patients about the drug. Doctors

sometimes prescribe Zyprexa for uses that are not provided for in the manufacturer's paper. These uses are known as "off-label" uses. Doctors prescribe drugs for off-label uses when studies in the medical literature support a use for the drug. These are uses that have not been reviewed or approved by the Federal Food and Drug Administration. Zyprexa is sometimes prescribed off-label for major depression, borderline personality, and agitation.

Your prescription for Zyprexa is - is not (**CIRCLE ONE**) an off-label prescription.

### **WARNINGS**

Various negative effects have been reported in patients treated with Zyprexa. These negative effects do not occur in everyone taking Zyprexa. Not all of the risks of taking Zyprexa are understood or known. As patient experience with Zyprexa continues and further study occurs, additional risks or adverse events not now known may be identified. Taking Zyprexa may involve risks that cannot be predicted or anticipated. Potential risks that are now known include the following.

1. Dramatic weight gain
2. Diabetes
3. High blood sugar, in some cases extreme and associated with ketoacidosis (build up of acid in the blood), coma or death.
4. Somnolence (sleepiness).
5. Increased LDL cholesterol (the "bad" cholesterol) and triglycerides and decreased HDL cholesterol (the "good" cholesterol.)
6. Impaired judgment, thinking or motor skills.
7. Orthostatic hypotension (a sudden fall in blood pressure that occurs when a person assumes a standing position) associated with dizziness, fainting and fast heart rate. Patients should be especially alert to this risk during the period of time it takes to determine the best dose of Zyprexa for the individual patient.
8. Elevated levels of ALT (SGPT) (enzymes made in liver cells which when elevated can be a marker of liver damage).
9. Disruption of the body's ability to reduce core body temperature.
10. Elevated prolactin (a hormone) levels, leading to breast swelling and discharge.
11. Difficulty swallowing.
12. Problems with heart rhythm
13. Increased risk of death in elderly patients over 80 years of age with dementia-related psychosis.
14. Strokes or transient ischemic attacks ("ministrokes") in elderly patients with dementia-related psychosis.
15. A potentially fatal group of symptoms sometimes referred to as Neurologic Malignant Syndrome.
16. Potentially irreversible tardive dyskinesia. This is a condition primarily characterized by random movements in the tongue, lips or jaw as well as

facial grimacing, movements of arms, legs, fingers and toes or even swaying movements of the trunk or hips.

17. Seizures.

**IMPORTANT INSTRUCTIONS WHEN TAKING ZYPREXA**

1. Take this medicine only as directed by your doctor. Do not take more of it and do not take it more often than your doctor ordered.
2. Because Zyprexa has the potential to impair judgment, thinking or motor skills and because it may cause drowsiness, until you are reasonably certain that Zyprexa does not cause these problems for you you should not drive or operate other hazardous machinery, or do jobs that require you to be alert, well-coordinated or able to think or see well.
3. Notify your doctor if you become pregnant or intend to become pregnant while taking Zyprexa.
4. Do not breast feed an infant while taking Zyprexa.
5. Because Zyprexa may interact adversely with other drugs, tell your doctor about all prescription or over the counter drugs you may be taking. Also tell your doctor if you plan to take any new prescriptions or over-the-counter-drugs you have not already disclosed. You should also tell your doctor about any vitamins or dietary supplements you take or start taking.
6. Zyprexa may make it more difficult for your body to cool itself down. Therefore, you should use care not to become overheated or dehydrated when taking Zyprexa.
7. Avoid alcohol while taking Zyprexa.
8. Tell your doctor if for any reason you stop taking Zyprexa or the dose your doctor has prescribed.
9. Some people taking Zyprexa have experienced the adverse events listed below. Some of these events occur more commonly than others. Tell your doctor as soon as possible if you experience any of the following events while taking Zyprexa:

• dizziness	• fainting
• fast heart rate	• involuntary movements
• stroke	• mini stroke

• changes in your cholesterol	• weight gain
• diabetes	• high blood sugar
• seizures	• sleepiness
• difficulty swallowing	• abnormal lab tests
• difficulty in moving	• increased appetite
• dry mouth	• constipation
• low blood pressure or high blood pressure	• discomfort following meals
• weakness	• back pain
• difficulty speaking	• difficulty remembering
• tremors	• unusual thirst
• difficulty seeing or blurred vision	• any physical condition unusual for you
• accidental injury	• chest pain
• vomiting	• skin discoloration
• swelling in your arms or legs	• joint pain
• difficulty sleeping	• abnormal walking
• irritation of the nose	• urinary incontinence
• urinary tract infection	• increased salivation
• confusion	• euphoria
• difficulty in coordination	• sore throat
• sweating	• acne
• dry skin	• difficulty breathing
• shortness of breath	• itching or burning of the vagina
• dental pain	• gassy bowel
• joint stiffness and	• abnormal dreams

twitching	
• pink eye and red eye	Difficulty urinating

10. Because weight gain is associated with Zyprexa, you should take steps to control your weight by exercising and controlling how much food you eat. Of course, your doctor and other staff will answer any questions you may have about exercise and weight control programs and any other matter relating to Zyprexa.
11. It is important that you keep your appointments with your doctor so your progress while taking Zyprexa can be monitored. Among other things, your doctor will monitor your:

• weight	• waist circumference
• blood pressure	• blood sugar levels
• blood test to determine risk of heart disease	activity level; blood count, liver functions, cardiogram

12. Tell your doctor if you or anyone in your family has or had:

• a problem being overweight or obese	• diabetes; high blood sugar
• high blood pressure	• heart disease
• abnormal cholesterol or other laboratory tests	• Neuroleptic malignant syndrome; seizures;liver disease; breast cancer

13. You should call your doctor if you experience any unusual side effects, even if they are not on this list.

### **ALTERNATIVES**

Zyprexa is one of a class of drugs known as atypical antipsychotics. This class of drugs is also sometimes referred to as second generation atypicals. Other drugs in the same class have different characteristics of risks and benefits. For instance, research shows an increased risk of diabetes when taking Zyprexa and Clozaril (clozapine). However, the data so far on Abilify (aripiprazole) and Geodon (ziprasidone) do not show an increased risk for diabetes. Clozaril and Zyprexa may be more appropriate for patients when other treatments have not been as affective. Your doctor will explain the alternatives to you and answer any questions you may have about alternative treatment

