# XXXX Pharmacy Name LOGO

XXXX Address

Phone: XXX Fax: XXX

## **INFORMED CONSENT AND WAIVER OF LIABILITY FOR**

**INVEGA SUSTENNA® (paliperidone palmitate) INJECTIONS INVEGA TRINZA® (3-month paliperidone palmitate) INJECTIONS**

This Informed Consent and Waiver of Liability (this “**Consent and Waiver**”) has been prepared to provide you with information regarding the risks and side effects of INVEGA SUSTENNA/TRINZA injections. It is important that you read this information carefully and completely. Please discuss any questions you may have with, or request any additional information you need from, the pharmacist, nurse, or your prescribing physician. Once you have read and understand this information, and had any questions addressed to your satisfaction, please sign and date this Consent and Waiver. ***Do not sign this Consent and Waiver and do not receive an INVEGA SUSTENNA/TRINZA injection if you have questions about or do not understand the information you have received or are not comfortable assuming the risks that may be associated with INVEGA SUSTENNA/TRINZA.***

Patient’s Name DOB / / Street Address City State Zip Code

## **PROPOSED TREATMENT**

INVEGA TRINZA® (3-month paliperidone palmitate) is a prescription medicine given by injection every 3 months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA® is used in people who have been treated with INVEGA SUSTENNA® (1-month paliperidone palmitate) for at least 4 months.

INVEGA SUSTENNA® is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA® is used to treat schizophrenia.

## **SIDE EFFECTS AND COMPLICATIONS**

INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

* Stroke in elderly people (cerebrovascular problems) that can lead to death

\* Neuroleptic Malignant Syndrome (NMS). NMS is a rare but very serious problem that can happen in people who receive INVEGA TRINZA® or INVEGA SUSTENNA®. NMS can cause death and must be treated in a hospital. Call your healthcare provider right away if you become severely ill and have any of these symptoms: high fever; severe muscle stiffness; confusion; loss of consciousness; changes in your breathing, heartbeat, and blood pressure

* problems with your heartbeat. These heart problems can cause death. Call your healthcare provider right away if you have any of these symptoms: passing out or feeling like you will pass out, dizziness, or feeling as if your heart is pounding or missing beats
* uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)
* metabolic changes. Metabolic changes may include high blood sugar (hyperglycemia), diabetes mellitus and changes in the fat levels in your blood (dyslipidemia), and weight gain
* low blood pressure and fainting
* changes in your blood cell counts
* · high level of prolactin in your blood (hyperprolactinemia). INVEGA TRINZA® and INVEGA SUSTENNA® may cause a rise in the blood levels of a hormone called prolactin (hyperprolactinemia) that may cause side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection
* problems thinking clearly and moving your body
* seizures
* difficulty swallowing that can cause food or liquid to get into your lungs
* prolonged or painful erection lasting more than 4 hours. Call your healthcare provider or go to your nearest emergency room right away if you have an erection that lasts more than 4 hours
* problems with control of your body temperature, especially when you exercise a lot or spend time doing things that make you warm. It is important for you to drink water to avoid dehydration.
* The most common side effects of INVEGA TRINZA® include: injection site reactions,

 weight gain, headache, upper respiratory tract infections, feeling restlessness or difficulty sitting still, slow movements, tremors, stiffness and shuffling walk.

* The most common side effects of INVEGA SUSTENNA® include: injection site reactions;

sleepiness or drowsiness; dizziness; feeling of inner restlessness or needing to be constantly moving; abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of your eyes.

Tell your physician if you have any side effect that bothers you or does not go away.

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

## **PATIENTS WHO SHOULD NOT USE INVEGA TRINZA® or INVEGA SUSTENNA®**

Do not receive INVEGA TRINZA® or INVEGA SUSTENNA® if you are allergic to paliperidone, paliperidone palmitate, risperidone, or any of the ingredients in INVEGA TRINZA® or INVEGA SUSTENNA®.

INVEGA TRINZA® and INVEGA SUSTENNA® are not for treating dementia-related psychosis.

## **THINGS TO TELL YOUR PRACTITIONER**

Before you receive INVEGA TRINZA® or INVEGA SUSTENNA®, tell your pharmacist, nurse, and/or physician about all your medical conditions, including if you:

* have had Neuroleptic Malignant Syndrome (NMS)
* have or have had heart problems, including a heart attack, heart failure, abnormal heart rhythm, or long QT syndrome
* have or have had low levels of potassium or magnesium in your blood
* have or have had uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)
* have or have had kidney or liver problems
* have diabetes or have a family history of diabetes
* have had a low white blood cell count
* have had problems with dizziness or fainting or are being treated for high blood pressure
* have or have had seizures or epilepsy
* have any other medical conditions
* are pregnant or plan to become pregnant. It is not known if INVEGA TRINZA® or INVEGA SUSTENNA® will harm your unborn baby

\* If you become pregnant while taking INVEGA TRINZA®, talk to your pharmacist, nurse, and/or physician about registering with the National Pregnancy Registry for

Aypical Antipsychotics. You can register by calling [1-866-961-2388 or visit http://](http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry) [womensmentalhealth.org/clinical-and-](http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry)research-programs/pregnancyregistry

* Infants born to women who are treated with INVEGA TRINZA® or INVEGA SUSTENNA® may have withdrawal symptoms or other symptoms such as tremors, muscle spasms, abnormal movement of arms and legs, and twitching of eyes.
* are breastfeeding or plan to breastfeed. INVEGA TRINZA® and INVEGA SUSTENNA® can pass into your breast milk and may harm your baby. You and yourr pharmacist, nurse, and/or physician should decide if you will receive INVEGA TRINZA® or INVEGA SUSTENNA® or breastfeed. You should not do both.

Tell your pharmacist, nurse, and/or physician about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show to your pharmacist and/or nurse when you get a new medicine.

Patients (particularly the elderly) taking antipsychotics with certain health conditions or those on long- term therapy should be evaluated by their healthcare provider for the potential risk of falls.

## **THINGS TO AVOID WHILE TAKING INVEGA TRINZA® or INVEGA SUSTENNA**®

* INVEGA TRINZA® and INVEGA SUSTENNA® may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how INVEGA TRINZA® or INVEGA SUSTENNA® affects you

\* avoid getting overheated or dehydrated

## **PATIENT CONSENT AND WAIVER OF LIABILITY**

**I acknowledge that I have carefully and fully read this Consent and Waiver and I understand the potential risks and side effects related to the use of INVEGA TRINZA® or INVEGA SUSTENNA® listed above and explained by my physician. I have been given the opportunity to ask questions and I have had all of my questions answered.**

**I acknowledge that PHARMACY NAME did not prescribe the medicine and is only performing the INVEGA TRINZA® or INVEGA SUSTENNA® injections through the pharmacist, and/or nurse at my request and with my authorization, which is hereby being given.**

**In acknowledgement of the foregoing, I, for myself, my heirs, assigns, and anyone acting on my behalf, hereby waive any and all claims against PHARMACY NAME and its principals, agents, and employees, and agree to hold each them harmless from any and all liability whatsoever, arising out of, in connection with, or in any way related to the use or administration of INVEGA TRINZA® or INVEGA SUSTENNA®.**

**I agree that this Consent and Waiver will be valid for each repeated injection of the following medicine:**

**INVEGA TRINZA® INVEGA SUSTENNA®**





Patient Signature Date

 

Signature of Practitioner who conducted the Name Informed Consent Discussion