

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 10/14/2011

Completion of this form is voluntary. If not completed, the medication cannot be administered without a court order unless in an emergency.
 This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First, MI)		ID Number	Living Unit	Birthdate
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antipsychotic Agent	Invega Sustenna (Paliperidone)	39mg-234 mg	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.

Recommended daily total dosage range of manufacturer, as stated in Physician's Desk Reference (PDR) or another standard reference.

This medication will be administered Orally Injection Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off Label' Use)

Include DSM IV diagnosis or the diagnostic "working hypothesis."

2. Alternative mode(s) of treatment other than or in addition to medications include

Note: Some of these would be applicable only in an inpatient environment.

- | | |
|--|--|
| <input type="checkbox"/> -Environment and / or staff changes | <input type="checkbox"/> -Rehabilitation treatments / therapy (OT, PT, AT) |
| <input type="checkbox"/> -Positive redirection and staff interaction | <input type="checkbox"/> -Treatment programs and approaches (habilitation) |
| <input type="checkbox"/> -Individual and / or group therapy | <input type="checkbox"/> -Use of behavior intervention techniques |

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of -Work Activities -Family Relationships -Social Functioning

Possible increase in symptoms leading to potential

- | | |
|---|---|
| <input type="checkbox"/> -Use of seclusion or restraints | <input type="checkbox"/> -Limits on recreation and leisure activities |
| <input type="checkbox"/> -Limits on access to possessions | <input type="checkbox"/> -Intervention of law enforcement authorities |
| <input type="checkbox"/> -Limits on personal freedoms | <input type="checkbox"/> -Risk of harm to self or others |
| <input type="checkbox"/> -Limit participation in treatment and activities | |

Other consequences

Note: These consequences may vary, depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

4. Possible side effects, warnings and cautions associated with this medication are listed below. This is not an all inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text such as the PDR or the United States Pharmacopoeia Dispensing Information (USPDI). As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects, in order to enhance care and treatment.

Continued – Possible side effects, warnings and cautions associated with this medication.

Common side effects of INVEGA® SUSTENNA® include: Reactions at the injection site Sleepiness Dizziness Feeling of inner restlessness Abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of the eyes

One risk of INVEGA® SUSTENNA® is that it may change your heart rhythm. This effect is potentially serious. You should talk to your doctor about any current or past heart problems. Because these problems could mean you're having a heart rhythm abnormality, contact your doctor IMMEDIATELY if you feel faint or feel a change in the way that your heart beats (palpitations).

High blood sugar and diabetes have been reported with INVEGA® SUSTENNA® and similar medicines. If you already have diabetes or have risk factors such as being overweight or a family history of diabetes, blood sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening. Call your doctor if you develop signs of high blood sugar or diabetes, such as being thirsty all the time, having to urinate or "pass urine" more often than usual, or feeling weak or hungry.

Weight gain has been observed with INVEGA® SUSTENNA® and other atypical antipsychotic medications. If you notice that you are gaining weight, please notify your doctor.

Some people may feel faint, dizzy, or may pass out when they stand up or sit up suddenly. Be careful not to get up too quickly. It may help if you get up slowly and sit on the edge of the bed or chair for a few minutes before you stand up. These symptoms may decrease or go away after your body becomes used to the medicine.

INVEGA® SUSTENNA® and similar medicines have been associated with decreases in the counts of white cells in circulating blood. If you have a history of low white blood cell counts or have unexplained fever or infection, then please contact your doctor right away.

INVEGA® SUSTENNA® and similar medicines can raise the blood levels of a hormone called prolactin and blood levels of prolactin remain high with continued use. This may result in some side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection.

If you have a prolonged or painful erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

Call your doctor right away if you start thinking about suicide or wanting to hurt yourself.

INVEGA® SUSTENNA® can make some people feel dizzy, sleepy, or less alert. Until you know how you are going to respond to INVEGA® SUSTENNA®, be careful driving a car, operating machines, or doing things that require you to be alert.

Neuroleptic Malignant Syndrome (NMS) is a rare, but serious side effect that could be fatal and has been reported with INVEGA® SUSTENNA® and similar medicines. Call the doctor right away if you develop symptoms such as a high fever, rigid muscles, shaking, confusion, sweating more than usual, increased heart rate or blood pressure, or muscle pain or weakness. Treatment should be stopped if you are being treated for NMS. Tardive Dyskinesia (TD) is a rare, but serious and sometimes permanent side effect reported with INVEGA® SUSTENNA® and similar medicines. Call your doctor right away if you start to develop twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the total dose received. This condition can also develop after a short period of treatment at low doses but this is less common. There is no known treatment for TD but it may go away partially or completely if the medicine is stopped.

One risk of INVEGA® SUSTENNA® is that it may change your heart rhythm. This effect is potentially serious. You should talk to your doctor about any current or past heart problems. Because these problems could mean you are having a heart rhythm abnormality, contact your doctor IMMEDIATELY if you feel faint or feel a change in the way that your heart beats (palpitations).

Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g. stroke, transient ischemic attack, including fatalities). INVEGA® SUSTENNA® is not approved for use in patients with dementia-related psychosis. **Neuroleptic Malignant Syndrome:** Manage with immediate discontinuation of drug and close monitoring. **QT Prolongation:** Increase in QT interval, avoid use with drugs that also increase QT interval and in patients with risk factors for prolonged QT interval. **Tardive Dyskinesia:** Discontinue drug if clinically appropriate. **Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. **Hyperglycemia and Diabetes Mellitus:** Monitor patients for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Monitor glucose regularly in patients with diabetes or at risk for diabetes. **Dyslipidemia:** Undesirable alterations have been observed in patients treated with atypical antipsychotics.

Weight Gain: Significant weight gain has been reported. Monitor weight gain. (5.6) **Hyperprolactinemia:** Prolactin elevations occur and persist during chronic administration. **Orthostatic Hypotension and Syncope:** Use with caution in patients with known cardiovascular or cerebrovascular disease and patients predisposed to hypotension. **Leukopenia, Neutropenia, and Agranulocytosis:** has been reported with antipsychotics, including INVEGA®, an oral form of paliperidone. Patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of INVEGA® SUSTENNA® should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. **Potential for Cognitive and Motor Impairment:** Use caution when operating machinery **Seizures:** Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. **Suicide:** Closely supervise high-risk patients **Administration:** For intramuscular injection only. Avoid inadvertent injection into a blood vessel.

Black Box Warning:

Increased Mortality in Elderly Patients with Dementia Related Psychosis

Elderly patients with dementia related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo controlled trials (modal duration of 10 weeks, largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug treated patients of between 1.6 to 1.7 times that seen in placebo treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. This drug is not approved for the treatment of patients with dementia-related psychosis.

See PDR, USPDI or US Hospital Formulary Service for all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager or psychologist.
4. I have the right to request a review at any time of my record, pursuant to ss. 51.30(4)(d) or 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager or agency / facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s) and the probable consequences, which may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES

DATE SIGNED

Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	
Client / Parent of Minor / Guardian (POA-HC) Comments		

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____