

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 12/17/2010

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 (Benzisoxazole)	Invega (Paliperidone)	6mg—12mg	

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.

- Environment and / or staff changes
- Positive redirection and staff interaction
- Individual and / or group therapy
- Rehabilitation treatments / therapy (OT, PT, AT)
- Treatment programs and approaches (habilitation)
- 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

- Use of seclusion or restraints
- Limits on access to possessions
- Limits on personal freedoms
- Limit participation in treatment and activities
- Limits on recreation and leisure activities
- Intervention of law enforcement authorities
- Risk of harm to self or others

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.

See Page 2

Client Initial _____ Date _____

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.

Check with your doctor immediately if any of the following side effects occur: Difficulty with speaking; drooling; fast, pounding, or irregular heartbeat or pulse; loss of balance control; muscle trembling, jerking, or stiffness; restlessness; shuffling walk; stiffness of limbs; twisting movements of body; uncontrolled movements, especially of face, neck, and back.

Other common side effects may include: fear or nervousness; headache; inability to sit still; nausea; need to keep moving; sleepiness or unusual drowsiness; weight gain.

Check with your doctor immediately if any of the following less common side effects occur: chest pain; cold sweats; confusion; cough; difficulty with swallowing; dizziness; excessive muscle tone; fainting; inability to move eyes; increased blinking or spasms of eyelid; increased blood pressure; loss of balance control; mask-like face; muscle tension or tightness; pain in arms or legs; slow heartbeat; slowed movements; slurred speech; sticking out tongue when not meaning to; tic-like (jerky) movements of head, face, mouth, and neck; trembling and shaking of fingers and hands; tremors; trouble with breathing, speaking, or swallowing; uncontrolled twisting movements of neck, trunk, arms, or legs; unusual facial expressions; unusual tiredness or weakness.

Other less common side effects may include: Acid or sour stomach; back pain; belching; blurred vision; dizziness, faintness, or lightheadedness when getting up from a lying or sitting position suddenly; dry mouth; fever; heartburn; indigestion; lack or loss of strength; stomach discomfort, upset, or pain; upper abdominal pain.

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.

Precautions While Using This Medicine

It is very important that your doctor check your progress at regular visits. This will allow your doctor to see if the medicine is working properly and to check for any problems or unwanted effects that may be caused by this medicine.

For diabetic patients: This medicine may affect blood sugar levels. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with your doctor .

This medicine may make you dizzy or drowsy. Avoid driving, using machines, or doing anything else that could be dangerous if you are not alert. You may also feel lightheaded when getting up suddenly from a sitting or lying position, so get up slowly.

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.

Client Initial _____ Date _____

Medication : Invega - (Paliperidone)

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 _____