

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 06/25/2020

Completion of this form is voluntary. If informed consent is not given, 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	Date of Birth
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antipsychotic/Mood Stabilizing Agent	Seroquel (quetiapine); Seroquel XR (quetiapine XR)	Quetiapine 50mg - 800mg Quetiapine XR 300 mg - 800mg	

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-5 diagnosis or the diagnostic impression ("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 restraint
- 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. 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.

Most Common Side Effects: constipation; drowsiness; dry mouth; indigestion; headache; agitation; weight gain; elevated cholesterol; elevated triglycerides; hypertension (high blood pressure); tachycardia (rapid, pulsating heart); increased appetite; fatigue.

Less Common Side Effects: pain; decreased strength and energy; increased muscle tone; EPS side effects (symptoms such as: muscle rigidity, muscle spasms, uncontrollable abnormal movements, excessive normal movements, shuffling of feet); increased sweating; stuffy or runny nose; orthostatic hypotension (dizzy upon standing from a sitting or lying position); swelling in the feet or ankles from fluid accumulation; acne; decreased appetite; diarrhea; increased incidence of urinary tract infections; abnormal dreams. Children on this medication may be more likely to have nausea or vomiting; dizziness, lightheadedness, or fainting, especially when getting up from a lying or sitting position; fever, chills, muscle aches, or sore throat; loss of balance control; mask-like face; shuffling walk; skin rash; slowed movements; stiffness of arms or legs; swelling of feet or lower legs; trembling and shaking of hands and fingers; trouble in breathing, speaking, or swallowing.

Rare Side Effects: Although rare, contact your doctor as soon as possible if any of the following occur: fainting; fast, pounding, or irregular heartbeat; QT prolongation of the heart rhythm; menstrual changes; unusual secretion of milk (in females); aggressive behavior; unable to focus or keep attention; migraines; restlessness, twitching, changes in vision; severe cough; difficulty breathing; excessive nose bleeds; increased incidence of upper respiratory tract infections; suicidal thoughts; hypertensive emergency (extremely elevated blood pressure); Stevens-Johnson syndrome (rash); rhabdomyolysis (symptoms of: generalized, severe muscle pain; muscle weakness; dark or decreased urine).

Caution:

- **Avoid alcohol**
This medicine may add to the effects of alcohol and other CNS depressants (medicines that make you drowsy or less alert). Check with your doctor before taking any other medications.
- **Fall risk**
This medication may cause dizziness and drowsiness which could increase the risk of falling. This is especially a caution in elderly patients and those with a history of falls.
- **Hyperglycemia**
Atypical antipsychotics, like Seroquel (quetiapine), have been associated with the development of hyperglycemia (high blood sugar), and, in extreme cases, may be associated with ketoacidosis, coma, or death. Monitor for symptoms of hyperglycemia such as: increased thirst, increased urination, feeling weak, and/ or feeling extreme hunger that does not go away with eating. If you believe you are having these symptoms, contact your doctor as soon as possible.
- **Driving and operating heavy machinery**
Quetiapine may cause drowsiness, especially during the first week of use. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert.
- **Orthostatic hypotension**
Dizziness, lightheadedness, or fainting may occur, especially when you get up from a lying or sitting position. Getting up slowly may help. If the problem continues or gets worse, check with your doctor.
- **QT prolongation**
Abnormal heart rhythm leading to fainting spells or sudden death, use in caution with risk factors (congenital long QT syndrome, history of prolonged QT, family history of prolonged QT or sudden cardiac death; concomitant use with other agents that prolong QT interval).
- **Do not crush extended release tablets**
Do not chew or crush the extended release tablets. The extended release tablets should be swallowed whole.
- **Seizures (convulsions)**
This medication increases the risk of experiencing a seizure in those at risk of seizures or in those with other conditions that lower the seizure threshold.
- **Tardive dyskinesia**
A syndrome of potentially irreversible, involuntary, abnormal movements can develop in patients treated with antipsychotic drugs. The prevalence of the syndrome appears to be highest among the elderly, especially elderly women. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.
- **Withdrawal**
Do not suddenly stop taking this medication as it could lead to symptoms of withdrawal. Talk with your doctor before stopping this medication.

Medication : Seroquel;
Seroquel XR - (quetiapine)

Warning: [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.

[Black Box Warning] Suicidal Ideation in Children, Adolescents, and Young Adults: Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in short term studies in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of this drug or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

Quetiapine is not FDA approved for use in pediatric patients under ten years of age.

See standard reference text for an 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 § 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 that 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 <input type="checkbox"/> Yes <input type="checkbox"/> No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received