

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 11/25/2015

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	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
Central Nervous System Agent	Strattera (atomoxetine)	Adults: 40mg—100 mg Children: Dose by body weight (up to 100 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 5 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.

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.

The most common side effects of this medication in Children Clinical Trials include: nausea, vomiting, fatigue, decreased appetite, abdominal pain, headache, and somnolence. Other side effects in children include headache, fatigue, irritability, decreased weight, and dizziness. The most common side effects of this medication in Adult Clinical Trials include: constipation, dry mouth, nausea, decreased appetite, erectile dysfunction, and urinary hesitation. Other side effects in adults include abdominal pain, insomnia, decreased interest in sexual intercourse, and fatigue.

Other less common side effects include: increased heart rate, increased blood pressure, dizziness, change in menstrual cycles for women, sleep disorder, and urinary retention.

Check with your doctor immediately if the following side effects occur: Hives, rash, irregular heartbeat/chest pain, psychotic/manic symptoms, induction of mixed/manic episode, worsening hostility/aggression, anxiety, agitation, suicidal thoughts, depression, erection lasting longer than 4 hours: dark colored urine, flu-like symptoms, right upper belly pain or tenderness, or yellow eyes or skin.

Avoid excessive alcohol usage, since it may increase the potential for Central Nervous System (CNS) effects such as dizziness, confusion, lightheadedness and orthostatic hypotension.

CONTRAINDICATIONS: hypersensitivity to atomoxetine, Monoamine Oxidase Inhibitors (MAOI) use or use within the last 2 weeks, narrow angle glaucoma, pheochromocytoma (elevated blood pressure and heart rate), severe cardiovascular disorders.

WARNINGS: Severe liver injury

Post marketing reports indicate that atomoxetine can cause severe liver injury. Rare cases of liver failure have been reported. Reported cases of liver injury occurred within 120 days of initiation of atomoxetine in the majority of cases with markedly elevated liver enzymes. Reactions may occur several months after therapy is started but laboratory abnormalities may continue to worsen several weeks after the drug is stopped.

Emergence of New Psychotic or Manic Symptoms: treatment emergent psychotic or manic episodes in children and adolescents without a prior history of psychotic illness or mania can be caused by atomoxetine at usual doses.

Screening for Bipolar disorder: concern for possible induction of mixed/manic episodes in patients at risk for bipolar disorder.

Aggressive behavior or hostility: monitor for appearance or worsening of aggressive behavior or hostility.

Serious Cardiovascular Events: Sudden Death and Pre-existing structural cardiac abnormalities or other serious heart problems.

Children and adolescents: sudden death has been reported in association with atomoxetine at usual doses in children with structural cardiac abnormalities or other serious heart problems. **Adults:** sudden death, stroke, and myocardial infarction (MI) have been reported in adults taking atomoxetine at usual doses for ADHD.

Priapism: painful and nonpainful penile erections lasting more than 4 hours have been reported for pediatric and adult patients on atomoxetine.

Growth: The weight and height of pediatric patients treated with atomoxetine lags behind that predicted by normative population data for the first 9 to 12 months of treatment.

BLACK BOX WARNING Increased risk of suicidal ideation in children or adolescents. No suicides occurred in clinical trials. Patients started on therapy should be monitored closely.

Suicidal Ideation: Atomoxetine increased the risk of suicidal ideation in short-term studies in children or adolescents with attention-deficit/hyperactivity disorder (ADHD). Anyone considering the use of atomoxetine in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

Pooled Study Data: Pooled analyses of short-term (6 to 18 weeks) placebo controlled trials of atomoxetine in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving atomoxetine compared to placebo. The average risk of suicidal ideation in patients receiving atomoxetine was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients). No suicides occurred in these trials. Atomoxetine is approved for ADHD in pediatric and adult patients. It is not approved for major depressive disorder.

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, 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 _____