

**INFORMED CONSENT FOR MEDICATION**

Dosage and / or Side Effect information last revised on 12/22/2017

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)	Oral: Adults: 40mg—100 mg per day in 1 or 2 divided doses Children over 6: Dose by body weight (up to 100 mg per day in 1 or 2 divided doses)	

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.

- |   |   |
|---|---|
| <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 restraint                   | <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. 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

More common side effects include headache, insomnia, drowsiness, dry mouth, nausea, vomiting, decreased appetite, constipation, erectile dysfunction.

#### Less Common Side Effects

Less common side effects include increased blood pressure, palpitations, cold extremities, syncope, flushing, dizziness, depression, irritability, decreased sex drive or ability, dyspepsia.

#### Rare Side Effects

Rare side effects include aggressive behavior, alopecia, angioedema, delusions, liver toxicity, panic attack.

#### BLACK BOX WARNING

**Suicidal ideation in children and adolescents:** 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. Comorbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Closely monitor patients who are started on therapy for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Advise families and caregivers of the need for close observation and communication with the prescribing health care provider.

**Pooled Study Data:** Pooled analyses of short-term (6- to 18-week), placebo-controlled trials of atomoxetine in children and adolescents (12 trials involving more than 2,200 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 with placebo. The average risk of suicidal ideation in patients receiving atomoxetine was 0.4% compared with none in placebo-treated patients. **No suicides occurred in these trials.**

#### WARNINGS:

**Hepatotoxicity** – Use may be associated with rare but severe hepatotoxicity, including hepatic failure: discontinue and do not restart if signs or symptoms of hepatotoxic reaction (ie jaundice, pruritus, flu-like symptoms, dark urine, right upper quadrant tenderness) or laboratory evidence of liver injury are noted. Majority of reported cases occurred within 120 days of initiation of therapy.

**Emergence of New Psychotic or Manic Symptoms** – Treatment-emergent psychotic or manic symptoms (hallucinations, delusional thinking, mania) may occur in children and adolescents without a prior history of psychotic illness or mania. Consider discontinuation of treatment if symptoms occur.

**Screening for bipolar disorder** – Therapy may induced mixed/manic episodes. Use caution in patients with comorbid bipolar disorder.

**Aggressive behavior or hostility** – New or worsening symptoms of hostility or aggressive behaviors have been associated with use, particularly with initiation of therapy.

**Serious Cardiovascular Events** – Use has been associated with serious cardiovascular events including sudden death in patients with preexisting structural cardiac abnormalities or other serious heart problems. Avoid use in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities. Patients should be carefully evaluated for cardiac disease prior to initiation of therapy. Monitor for symptoms of exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during treatment.

**Priapism** – Prolonged and painful erections have been reported (rarely) with methylphenidate and atomoxetine use in pediatric and adult patients.

See PDR 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