

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

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.

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.

The most common side effects of this medication may include: Acid or sour stomach; belching; bleeding between periods; change in amount of bleeding during periods; change in pattern of monthly periods; cough; decreased appetite; decreased interest in sexual intercourse; decrease in frequency of urination; decrease in urine amount; difficulty having a bowel movement (stool); difficulty in passing urine (dribbling); dizziness; dry mouth; fever; headache; heartburn; heavy bleeding; inability to have or keep an erection; indigestion; irritability; loss in sexual ability, desire, drive, or performance; nausea; pain or tenderness around eyes and cheekbones; painful urination; shortness of breath or troubled breathing; sleepiness or unusual drowsiness; sleeplessness; stomach discomfort, upset, cramps, or pain; stuffy or runny nose; tightness of chest or wheezing ; trouble sleeping; unable to sleep; unusual drowsiness, dullness, tiredness, weakness, or feeling of sluggishness; unusual stopping of menstrual bleeding; unusual tiredness or weakness; vomiting.

Less common side effects may include: Abnormal dreams; abnormal orgasm; back pain; blistering, crusting, irritation, itching, or reddening of skin; bloated, full feeling; burning, crawling, itching, numbness, prickling, "pins and needles," or tingling feelings; change in hearing; change or problem with discharge of semen; chills; cold sweats; confusion; cough; cracked, dry, scaly skin; crying; decreased weight; diarrhea; difficulty with moving; dizziness, faintness, or lightheadedness when getting up from a lying or sitting position suddenly; ear drainage; earache or pain in ear; excess air or gas in stomach or intestines; feeling of warmth, redness of the face, neck, arms, and occasionally, upper chest; feeling unusually cold; frequent urination; general feeling of discomfort or illness; groin pain; increased or sudden sweating; joint pain; loss of appetite; mood swings; muscle aches, cramping, pains, or stiffness; pain or burning with urination; passing gas; shivering; sinus headache; sleep disorder; swelling of skin; swollen joints; swollen, tender prostate.

Check with your doctor immediately if the following side effects occur: Hives or welts; irregular heartbeat ; itching; large, hive-like swelling on face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs; redness of skin; skin rash.

Check with your doctor immediately if any of the following rare side effects occur: Dark colored urine; flu-like symptoms; right upper belly pain or tenderness; yellow eyes or skin

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

BLACK BOX WARNING

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.

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 : Strattera - (atomoxetine)

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 _____