

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/25/2020

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/antidepressant	Symbyax (Olanzapine + Fluoxetine)	<i>Initial dose:</i> 6 mg olanzapine/25 mg fluoxetine capsule <i>Maximum dose:</i> 18 mg olanzapine +75 mg fluoxetine capsule	

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.

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

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: dizziness; generalized swelling; drowsiness; increased appetite; dry mouth; weight gain; fatigue; increased liver enzymes; increased cholesterol; increased prolactin.

Less Common Side Effect: orthostatic hypotension (dizziness when getting up from a sitting or lying position); QT-interval prolongation of the heart; feeling too warm; Mania (having high energy or participating in activity that you feel like you cannot control); cannot focus or concentrate; feeling restless, like you cannot sit still; anxiety; having abnormal thoughts; nervousness; generalized pain; suicidal thoughts or actions (If you do experience this, call your doctor immediately); memory loss; sensitivity of the skin to the sun; unable to achieve erection; breast pain; weight loss; chills; more frequently feel the need to urinate; menstrual changes; heartburn; upset stomach; gas; abdominal bloating or pain; tremor; joint pain; muscle or back pain; blurry vision; fever; stuffy nose.

Rare Side Effects: Although rare, check with your doctor immediately if you experience the following: change in the amount of urine; muscle twitching; lip smacking or other uncontrolled movements; weakness on one side of body; irregular or fast heartbeat; difficulty swallowing; seizures; Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with olanzapine exposure. DRESS may present with a rash, fever, and/or swollen lymph nodes and could lead to body-wide complications. DRESS is sometimes fatal. Discontinue Symbyax if DRESS is suspected; Serotonin syndrome (symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., fast heart rate, high or low blood pressure, dizziness, excessive sweating, feeling too warm, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, twitching, muscle spasms, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea); bloating or swelling of face, arms, hands, lower legs, or feet; body aches or pain; confusion; congestion; cough; delusions; dementia; dryness or soreness of throat; hoarseness; rapid weight gain; shakiness in legs, arms, hands, or feet feet; tender, swollen glands in neck; tingling of hands or feet; trouble swallowing; voice changes.

Caution

- **Sexual dysfunction**
This drug has the potential to decrease sexual function or desire. If this becomes bothersome, please call your doctor.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with olanzapine exposure. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. DRESS is sometimes fatal. Discontinue SYMBYAX if DRESS is suspected.
- **Serotonin syndrome**
The development of a potentially life-threatening serotonin syndrome has been reported with SNRIs and SSRIs, including SYMBYAX, alone but particularly with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, and St. John's Wort) and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome.
- **Extrapyramidal symptoms (EPS)**
Patients have reported muscle spasms of the neck and back, shuffling walk, tic-like (jerky) movements of the head, face and neck; trembling and shaking of the hands and fingers; inability to move eyes; mask-like face; loss of balance control; blurred vision; difficulty speaking or swallowing. Additionally, though not common, Tardive Dyskinesia has been reported. Tardive Dyskinesia presents with lip smacking or puckering, puffing of cheeks, rapid or fine worm-like movement of tongue, uncontrolled chewing movement, or uncontrolled movements of arms and legs may occur and may not go away after stopping use of the medication.
- **Neuroleptic Malignant Syndrome (NMS)**
Use may be associated with NMS. Monitor for changes in thinking, fever, muscle stiffness, and/ autonomic instability (unable to exercise, abnormal sweating, loss of appetite, loss of bladder control, difficulty with ejaculation, blurry vision). Call your doctor as soon as possible if you believe you may have NMS.
- **Rash**
Fluoxetine use has been associated with occurrences of significant rash and allergic reactions. Discontinue if underlying cause of rash cannot be identified.
- **Driving and operating heavy machinery**
Symbyax may cause drowsiness or dizziness, which could make driving, operating heavy machinery, or participating in other activities requiring alertness dangerous. Be sure to know how this medication affects you before participating in these activities.
- **Blood disorder**
Check with your doctor immediately if you develop fever, chills, sore throat, or sores in the mouth. These may be signs of a very serious blood problem that has occurred rarely in patients taking Symbyax. This medication also has the potential to increase bleeding/
- **Orthostatic hypotension**
Orthostatic hypotension is when one feels dizzy while getting up from a lying or sitting position. Getting up slowly may help. If this problem continues or gets worse, check with your doctor.

- **QT prolongation**
This drug has the potential to affect the QT interval of the heart, which, in rare cases, can lead to a fatal arrhythmia. This medication should be used with caution in those have a history of QT prolongation, as well as those who have multiple QT prolonging risk factors.
- **Fractures**
Bone fractures have been associated with antidepressant treatment.
- **Anticholinergic effects**
May cause anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention).
- **Weight gain**
This medication has been associated with increased appetite and weight gain.
- **Seizure**
This medication has the potential, in rare cases, cause individuals to experience a seizure. Caution should be exercised in those who have a history of seizures.
- **Withdrawal**
This medication should not be suddenly stopped, as this could cause an individual to experience symptoms of withdrawal. Please speak with your physician before stopping this medication.

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.

Warning: [Black Box Warning]: Antidepressants and Suicidality

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. This drug is not approved for use in pediatric patients.

MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA—Close observation for suicidal thinking or unusual changes in behavior.

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