

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 |
|------------------------------|--------------------------------------|---|--------------------------|
| Antipsychotic/antidepressant | Symbyax (Olanzapine + Fluoxetine) | Once Daily at evening beginning at 6mg/25mg capsule 18mg/75mg capsule maximum | |

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.

- | | |
|--|--|
| <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 restraints | <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 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 are: Dizziness, drowsiness, diarrhea, dry mouth, increased appetite, weight gain, trouble sleeping, or joint pain.

Check with your doctor immediately if any of the following side effects occur: 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; fever; hoarseness; rapid weight gain; runny nose; shakiness in legs, arms, hands, feet; tender, swollen glands in neck; tingling of hands or feet; trembling or shaking of hands or feet; trouble in swallowing; unusual weight gain or loss; voice changes.

Less common side effects include: Change or problem with discharge of semen; decreased interest in sexual intercourse; difficulty in moving; inability to have or keep an erection; loss in sexual ability, desire, drive, or performance; muscle pain or stiffness; not able to have an orgasm; pain, swelling, or redness in joints; tooth disorder; twitching.

Check with your doctor immediately if any of the following side effects occur: 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; fever; hoarseness; rapid weight gain; runny nose; shakiness in legs, arms, hands, feet; tender, swollen glands in neck; tingling of hands or feet; trembling or shaking of hands or feet; trouble in swallowing; unusual weight gain or loss; voice changes.

Although rare, check with your doctor immediately if you experience the following: fever, muscle stiffness, change in the amount of urine, facial or body muscle twitching, lip smacking or other uncontrolled movements, tremor, weakness on one side of body, irregular or fast heartbeat, difficulty swallowing, seizures.

Males: In the very unlikely event you have a painful, prolonged erection, stop using this drug and seek immediate medical attention.

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.

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 PDR, USPDI or US Hospital Formulary Service for all-inclusive list of side effects.

Client Initial _____ Date _____

Medication : Symbyax - (Olanzapine + Fluoxetine)

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.

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 _____