

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/08/2016

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
Antipsychotic Agent (phenothiazine)	(thioridazine)	25mg - 800mg	

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: Constipation (mild); decreased sweating; dizziness; drowsiness; dryness of mouth; nasal congestion.

Check with your doctor as soon as possible if any of the following side effects occur: Blurred vision, change in color vision, or difficulty in seeing at night; fainting; loss of balance control; mask-like face; restlessness or need to keep moving; shuffling walk; stiffness of arms or legs; trembling and shaking of hands and fingers.

Check with your doctor immediately if any of the following side effects occur: Inability to move eyes; increased blinking or spasms of eyelid; lip smacking or puckering; muscle spasms of face, neck, body, arms, or legs causing unusual postures or unusual expressions on face; puffing of cheeks; rapid or worm-like movements of tongue; sticking out of tongue; tic-like or twitching movements; trouble in breathing, speaking, or swallowing; uncontrolled chewing movements; uncontrolled movements of arms or legs; uncontrolled twisting movements of neck, trunk, arms, or leg.

Less Common Side Effects

Less common side effects include: Changes in menstrual period; decreased sexual ability; increased sensitivity of eyes to light; rough or “fuzzy” tongue; secretion of milk (unusual); swelling or pain in breasts; watering of mouth; weight gain (unusual).

Check with your doctor as soon as possible if any of the following side effects occur: Difficulty in urinating; skin rash; sunburn (severe).

Rare Side Effects

Stop taking this medicine and get emergency help immediately if any of the following effects occur:

Symptoms of neuroleptic malignant syndrome: Confusion (severe) or coma; difficult or fast breathing; drooling; fast heartbeat; high or low (irregular) blood pressure; increased sweating; loss of bladder control; muscle stiffness (severe); trembling or shaking; trouble in speaking or swallowing.

Check with your doctor immediately if the following effects occur: Irregular or slow heart rate; recurrent fainting.

Check with your doctor as soon as possible if the following effects occur: Abdominal or stomach pains; aching muscles and joints; agitation, bizarre dreams, excitement, or trouble in sleeping; bleeding or bruising (unusual); chest pain; clumsiness; confusion (mild); constipation (severe); convulsions (seizures); dark urine; fever and chills; hair loss; headaches; hot, dry skin or lack of sweating; itchy skin (severe); muscle weakness; nausea, vomiting, or diarrhea; pain in joints; prolonged, painful, inappropriate erection of the penis; redness of hands; shivering; skin discoloration (tan or blue-gray); sore throat and fever; sores in mouth; unusual bleeding or bruising; unusual tiredness or weakness; yellow eyes or skin.

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.

--QTc Prolongation is dose related. Torsades de pointes type arrhythmias and sudden death.

--Reserved for use only in refractory schizophrenia failed to show an acceptable response to adequate course of other antipsychotics.

--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.

MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA

- Baseline and periodic ECG and serum potassium during therapy
- If baseline QTc > 450 msec do not initiate therapy
- If QTc > 500 msec during therapy, discontinue therapy
- Contraindicated for use with Cytochrome P450 2D6 inhibitors and agents known to prolong QTc interval
- Contraindicated for use in patients with history of cardiac arrhythmias or congenital long QT syndrome

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