

**INFORMED CONSENT FOR MEDICATION**

**Dosage and / or Side Effect information last revised on 05/09/2016**

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
Antianxiety Agent (benzodiazepine)	Tranxene (clorazepate)	3.75 - 60mg	

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.

The most common side effects include clumsiness or unsteadiness, dizziness or lightheadedness and drowsiness; slurred speech

Less common side effects include anxiety; confusion (may be more common in the elderly); fast, pounding, or irregular heartbeat; mental depression; abdominal or stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dryness of mouth or increased thirst; false sense of well-being; headache; increased bronchial secretions or watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness .

Rare side effects include abnormal thinking, including disorientation, delusions (holding false beliefs that cannot be changed by facts), or loss of sense of reality; agitation; behavior changes, including aggressive behavior, bizarre behavior, decreased inhibition, or outbursts of anger; convulsions (seizures); hallucinations (seeing, hearing, or feeling things that are not there); hypotension (low blood pressure); muscle weakness; skin rash or itching; sore throat, fever, and chills; trouble in sleeping; ulcers or sores in mouth or throat (continuing); uncontrolled movements of body, including the eyes; unusual bleeding or bruising; unusual excitement, nervousness, or irritability; unusual tiredness or weakness (severe); yellow eyes or skin

There have been reports of patients experiencing intense urges to gamble, increased sexual urges, and other intense urges, and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone and that are generally used for the treatment of Parkinson's disease, including amantadine. Although it is not proven that the medications caused these events, these urges were reported to have stopped in some cases when the dose was reduced or the medication was stopped. Prescribers should ask patients about the development of new or increased gambling urges, sexual urges or other urges while being treated with amantadine. Patients should inform their physician if they experience new or increased gambling urges, increased sexual urges or other intense urges while taking Amantadine Hydrochloride Capsules, USP. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking Amantadine Hydrochloride Capsules, USP.

#### **WARNINGS**

**Use in Depressive Neuroses or Psychotic Reactions:** Clorazepate is not recommended for use in depressive neuroses or in psychotic reactions.

**Use in Children:** Because of the lack of sufficient clinical experience, clorazepate is not recommended for use in patients less than 9 years of age.

**Interference with Psychomotor Performance:** Patients taking clorazepate should be cautioned against engaging in hazardous occupations requiring mental alertness, such as operating dangerous machinery including motor vehicles.

**Concomitant Use with CNS Depressants:** Since clorazepate has a central nervous system depressant effect, patients should be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effects of alcohol may be increased.

**Physical and Psychological Dependence:** Withdrawal symptoms (similar in character to those noted with barbiturates and alcohol) have occurred following abrupt discontinuance of clorazepate. Withdrawal symptoms associated with the abrupt discontinuation of benzodiazepines have included convulsions, delirium, tremor, abdominal and muscle cramps, vomiting, sweating, nervousness, insomnia, irritability, diarrhea, and memory impairment. The more severe withdrawal symptoms have usually been limited to those patients who had received excessive doses over an extended period of time. Generally milder withdrawal symptoms have been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months. Consequently, after extended therapy, abrupt discontinuation of clorazepate should generally be avoided and a gradual dosage tapering schedule followed.

Caution should be observed in patients who are considered to have a psychological potential for drug dependence.

Evidence of drug dependence has been observed in dogs and rabbits, which was characterized by convulsive seizures when the drug was abruptly withdrawn or the dose was reduced; the syndrome in dogs could be abolished by administration of clorazepate.

**Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including clorazepate, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.

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