

INFORMED CONSENT FOR MEDICATION

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
Benzoquinolizine- central nervous system agent	Xenazine® (tetrabenazine)	12.5 mg - 50 mg/day	

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.

- ☐ Environment and/or staff changes
- ☐ Rehabilitation treatments/therapy (OT, PT, AT)
- ☐ Positive redirection and staff interaction
- ☐ Treatment programs and approaches (habilitation)
- ☐ Individual and/or group therapy
- ☐ 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 restraint
- ☐ Limits on recreation and leisure activities
- ☐ Limits on access to possessions
- ☐ Intervention of law enforcement authorities
- ☐ Limits on personal freedoms
- ☐ Risk of harm to self or others
- ☐ 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.

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: Nausea, insomnia, anxiety, depression, fatigue, dysphagia, akathisia, parkinsonism, depression, upper respiratory infection, falls

Less Common Side Effects: Suicidal thoughts, decrease in appetite, vomiting, ecchymosis, dizziness, dysarthria, headache, impairment of balance, sedation, somnolence, tardive dyskinesia, unsteady when walking, agitation, impaired cognition, irritability, obsessive behavior, restlessness, suicidal thoughts and behavior, dysuria, bronchitis, dyspnea, pneumonia

Rare Side Effects

Caution:

Precautions:

- **Cardiovascular**

Avoid use in patients with congenital long QT syndrome or with a history of cardiac arrhythmias; increased risk of QT prolongation. Bradycardia; may increase the risk of torsade de pointes and/or sudden death. Hypokalemia may increase the risk of torsade de pointes and/or sudden death. Hypomagnesemia may increase the risk of torsade de pointes and/or sudden death. Hypotension has been reported.

- **Endocrine**

Hyperprolactinemia may occur; monitoring is recommended.

- **Gastrointestinal**

Dysphagia has been reported.

- **Hepatic**

Use in CYP2D6 poor metabolizers will result in increased drug exposure. CYP2D6 genetic testing should be conducted prior to administering doses greater than 50 mg/day.

- **Neurologic**

Neuroleptic Malignant Syndrome, potentially fatal, has been reported; discontinue use immediately if occurs. Sedation and somnolence have been reported. Akathisia and parkinsonism have been reported; dosage adjustment and discontinuation may be necessary. Tardive dyskinesia, potentially irreversible, may develop.

- **Ophthalmic**

Accumulation and toxicity in melanin-containing tissues may occur after extended use.

- **Psychiatric**

Depression and suicide have been reported; monitoring is recommended. Worsening in mood, cognition, rigidity, and functional capacity has been reported; may be due to side effects of medication or disease progression. Use of other drugs that are known to prolong QTc, including antipsychotic medications (e.g., chlorpromazine, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), class 1A (e.g., quinidine, procainamide) and class III (e.g., amiodarone, sotalol) antiarrhythmics, or any other medication known to prolong the QTc interval; should be avoided.

Warning: Black Box Warning: Oral tablets

Suicidal thoughts: Tetrabenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of tetrabenazine must balance the risks of depression and suicidality with the clinical need for control of chorea. Close observation of patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior should accompany therapy. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician. Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. Tetrabenazine is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.

Syndrome Note: Neuroleptic malignant syndrome: Clinical signs may include hyperpyrexia, muscle rigidity, altered mental status, autonomic instability, rhabdomyolysis, acute renal failure, myoglobinuria, or increases in creatinine phosphokinase. Untreated or inadequately treated extrapyramidal disorders may present with similar signs or symptoms.

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