

## INFORMED CONSENT FOR MEDICATION

**Dosage and / or Side Effect information last revised on 07/13/2020**

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 Agent (dibenzoxazepine)	Loxitane (loxapine)	20 mg – 250 mg	

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:** muscle spasms of the neck and back; constipation; drowsiness; dizziness; faintness; dry mouth; difficulty breathing, especially in those with a respiratory condition; difficulty with urination; nasal congestion; altered taste.

**Less Common Side Effects:** constipation (severe); changes in menstrual period; decreased sexual ability; increased sensitivity of skin to sunlight (skin rash, itching, redness or other discoloration of skin or severe sunburn); unusual secretion of milk in women; unusual weight gain; trouble with sleeping; inability to move eyes; shuffling walk; tic-like (jerking) movements of the head, face and neck; trembling and shaking of the hands and fingers; loss of balance control; blurred vision; mask-like face; difficulty speaking or swallowing; Tardive Dyskinesia-(lip smacking or puckering, puffing of cheeks, rapid or fine worm-like movement of tongue, uncontrolled chewing movement, uncontrolled movements of arms and legs may occur and may not go away after stopping use of the medication).

**Rare Side Effects:** Although rare, please contact your doctor as soon as possible if any of the following occur: convulsions or seizures; difficult or fast breathing; fast heartbeat or irregular pulse; fever; high or low blood pressure; increased sweating; loss of bladder control; severe muscle stiffness; development of breasts in males; unusually pale skin, unusual tiredness or weakness; sore throat; increased blinking or spasms of eyelid; uncontrolled twisting movement of neck, trunk, arms, or legs; unusual bleeding or bruising; unusual facial expressions or body positions; yellow eyes or skin. Potentially fatal blood cell abnormalities which may be prevented by careful monitoring and regular lab tests.

### Caution

- **Neuroleptic Malignant Syndrome (NMS)**  
Neuroleptic malignant syndrome may present with symptoms of confusion (severe), 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, and/or trouble with speaking or swallowing.
- **Driving and operating heavy machinery**  
This medication may make you dizzy or drowsy, which can make it dangerous to drive, operate heavy machinery, or participate in any other activity that could be hazardous if not fully alert. Wait until you know how this medication affects you before engaging in these activities.
- **Orthostatic hypotension**  
You may feel lightheaded when getting up suddenly from a sitting or lying position, so take caution by getting up slowly.
- **Extrapyramidal symptoms (EPS)**  
Extrapyramidal symptoms involve excessive normal and abnormal movements that may be uncontrollable. Symptoms to look out for include: 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; 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.
- **Seizures**  
This medication has the potential to lower the seizure threshold. Individuals with a history of seizures should be cautious when taking this medication and report any adverse events to their doctor.
- **Fall risk**  
This medication may make individuals drowsy and dizzy, which can lead to falls. Older individuals and people with a history of falls should be cautious when taking this medication.
- **Withdrawal**  
Do not suddenly stop taking this medication as it could cause you to experience withdrawal symptoms. Please speak with your doctor 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.

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