

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/25/2020

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
Antidepressant	Serzone (nefazodone)	Initial: 200 mg daily Elderly initial: 100 mg daily Effective Range: 300 mg – 600 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: headache; drowsiness; dizziness; insomnia (difficulty falling asleep or staying asleep); agitation; dry mouth; nausea; constipation; muscle weakness.

Less Common Side Effects: bladder pain; cough or hoarseness; diarrhea; excessive muscle tone leading to muscle stiffness; eye pain; frequent urge to urinate; generalized itching; muscle tension or tightness; pain during sexual intercourse; painful, burning, or difficult urination; shortness of breath, tightness in chest, or wheezing; stomach pain; thick, white vaginal discharge with no odor or with a mild odor; breast pain; generalized slowing of mental and physical activity; increased thirst; loss of strength or energy; muscle weakness; blurred vision or other changes in vision; clumsiness or unsteadiness; lightheadedness or fainting; ringing in the ears; skin rash or itching; abnormal dreams; confusion; diarrhea; flushing or feeling of warmth; heartburn; increased appetite; increased cough; memory problems; nausea; swelling of arms or legs; tingling, burning, or prickly sensations; tremor; vomiting.

Rare Side Effects: Although rare, check with your doctor as soon as possible if any of the following side effects occur: asthma; bleeding from the rectum; bloody or black, tarry stools; change in sexual desire or performance; chest pain; double vision; dry eyes; ear pain; fainting; fast heartbeat; fever, chills, or sore throat; hallucinations (seeing, hearing, or feeling things that are not there); hives; increased sense of hearing; increased sensitivity to sun; irritation or soreness of mouth; kidney stones; large pupils of eyes; lower back, side, or stomach pain; menstrual changes; mood or mental changes; nerve pain or twitching; pelvic pain; problems in speaking; problems with urination; prolonged, painful, inappropriate penile erection; red or irritated eyes; sensitivity of eyes to light; swelling of face; swollen glands; talking, feeling, and acting with excitement and activity you cannot control; unusual bleeding or bruising; unusual feeling of well-being; unusual tiredness or weakness; vomiting of blood or material that looks like coffee grounds; unexpected or excess milk flow from breasts; swelling of the breasts or breast soreness in males.

Caution

- **Liver failure**
This medicine may cause serious problems with your liver. Call your doctor right away for any of the following problems. Abdominal pain, nausea, vomiting, yellow eyes or skin, dark colored urine, light-colored stools, feeling very tired or weak.
- **Driving and operating heavy machinery**
This medicine may cause some people to become drowsy. If this occurs, do not drive, use machines, or do anything else that could be dangerous if you are not alert .
- **Orthostatic hypotension**
Dizziness, lightheadedness, or fainting may occur, especially when you get up from a lying or sitting position. Getting up slowly may help. If this problem continues or gets worse, check with your doctor.
- **Fractures**
This medication has been associated with bone fractures.
- **Sexual dysfunction**
This medication has been associated with rare reports of a decrease in sexual desire or function.
- **Seizure**
This medication may increase the risk of experiencing a seizure. This risk may be further increased in those who have a history of seizures.
- **Withdrawal**
You should not suddenly stop taking this medication as it could cause you to experience symptoms of withdrawal. Please speak with your doctor before starting this medication.

Before having any kind of surgery, dental treatment, or emergency treatment, tell the medical doctor or dentist in charge that you are using this medicine. Patients being treated with antidepressants for clinical worsening of the symptoms of depression, for the emergence of suicidality, and for the emergence of a variety of other symptoms that may represent a worsening of the patient's condition.

Warning: [Black Box Warning]: Hepatic failure:

Life-threatening cases have been reported with use. The reported rate in the U.S. is approximately 1 case of liver failure resulting in death or transplant per 250,000 to 300,000 patient-years of nefazodone treatment. The total patient-years is a summation of each patient's duration of exposure expressed in years. Ordinarily, treatment with nefazodone should not be initiated in individuals with active liver disease or elevated baseline serum transaminases. There is no evidence that pre-existing liver disease increases the likelihood of developing liver failure; however, baseline abnormalities can complicate patient monitoring. Patients should be advised to be alert for signs and symptoms of liver dysfunction, report immediately to doctor. Nefazodone should be discontinued if clinical signs or symptoms suggest liver failure.

Warning: [Black Box Warning]: 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

- Do not initiate therapy in patients with active liver disease or elevated baseline serum transaminases. There is no evidence that pre-existing liver disease increases risk of liver failure, but it can complicate patient monitoring.
- Withdraw therapy if serum AST or serum ALT > 3 times upper limit of normal. Should not be considered for re-treatment.
- Close observation for suicidal thinking or unusual changes in behavior.

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