

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/16/2017

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
Antidepressant	Viibryd (vilazodone)	10mg – 40mg	

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

The most common adverse reactions (incidence \geq 5% and at least twice the rate of placebo) are: diarrhea, nausea, vomiting, and insomnia.

Less Common Side Effects

Gastrointestinal disorders: Dry mouth, Dyspepsia, Flatulence, Gastroenteritis.

Nervous system disorders: Dizziness, Somnolence, Paresthesia, Tremor.

Psychiatric disorders: Abnormal dreams, Libido decreased, Restlessness, Orgasm abnormal.

General disorders: Fatigue, Feeling jittery.

Cardiac disorders: Palpitations.

Musculoskeletal and connective tissue disorders: Arthralgia.

Reproductive system and breast disorders: Delayed ejaculation, Erectile dysfunction.

Metabolism and nutrition disorders: Increased appetite.

Caution

Clinical Worsening/Suicide Risk: Monitor patients for clinical worsening and suicidal thinking or behavior. **Serotonin Syndrome:** Serotonin syndrome has been reported with SSRIs and SNRIs, including VIIBRYD, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone and St. John's Wort). If such symptoms occur, discontinue VIIBRYD and initiate supportive treatment. If concomitant use of VIIBRYD with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. **Seizures:** Can occur with treatment. Use with caution in patients with a seizure disorder. **Abnormal Bleeding:** Treatment can increase the risk of bleeding. Use with caution in association with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation. **Activation of Mania/Hypomania:** Can occur with treatment. Screen patients for bipolar disorder. **Discontinuation of Treatment with VIIBRYD:** A gradual reduction in dose is recommended rather than an abrupt cessation. **Hyponatremia:** Can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Warning

1. Suicidal thoughts or actions:

- VIIBRYD and other antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment or when the dose is changed.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
- New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
- Pay particular attention to such changes when VIIBRYD is started or when the dose is changed. Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms. Call your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:
- Attempts to commit suicide or acting on dangerous impulses.
- Acting aggressive or violent.
- Thoughts about suicide or dying.
- New or worse depression.
- New or worse anxiety or panic attacks.
- Feeling agitated, restless, angry, or irritable.
- Trouble sleeping.
- An increase in activity or talking more than what is normal for you (mania).
- Other unusual changes in behavior or mood.

2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions:

Agitation, hallucinations, coma or other changes in mental status, coordination problems or muscle twitching (overactive reflexes) fast heartbeat, high or low blood pressure sweating or fever, nausea, vomiting, or diarrhea, muscle stiffness or tightness.

3. **Abnormal bleeding:** VIIBRYD and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a nonsteroidal anti-inflammatory drug (NSAID), or aspirin.
4. **Seizures or convulsions.**
5. **Manic episodes:** greatly increased energy, severe trouble sleeping, racing thoughts, reckless behavior, unusually grand ideas excessive happiness, or irritability, talking more or faster than usual.
6. **Low salt (sodium) levels in the blood.** Elderly people may be at greater risk for this. Symptoms may include: headache, weakness or feeling unsteady, confusion, problems concentrating or thinking or memory problems.

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