

INFORMED CONSENT FOR MEDICATION
Dosage and / or Side Effect information last revised on 05/28/2021

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
Opioid Blocker	Vivitrol injection, Revia tablets (Naltrexone)	Tablets: 12.5 mg to 50 mg Injection: 380 mg IM once per month	

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: Injection site hardening of the skin, injection site itching, injection site irritation or reaction, abdominal pain, diarrhea, loss of appetite, nausea, vomiting, muscle pain, dizziness, headache, fainting, difficulty sleeping, and lack of energy.

Less Common Side Effects: Depression, feeling nervous, and anxiety.

Rare Side Effects: Injection site necrosis, deep venous thrombosis, hepatitis, hypersensitivity reaction, eosinophilic pneumonia, retinal artery occlusion, pulmonary thromboembolism, increased creatine kinase levels, and suicidal ideation.

Caution:

- **Withdrawal**
Precipitated opioid withdrawal has been reported in alcohol-dependent patients where the prescriber was unaware of additional use of opioids; report to your prescriber any opioid use prior to starting naltrexone. Abrupt opioid withdrawal may lead to abnormal findings, including acute liver injury. Vulnerability to overdose exists for individuals who try to overcome the blockade effect of naltrexone, even at lower doses than had previously been tolerated.
- **Use of Opioid Analgesics (pain relievers)**
Use of opioid pain relievers with naltrexone may induce withdrawal as noted earlier. Use of naltrexone includes carrying an ID alert or card so that emergency responders are aware of the contraindication with opioid pain relievers.
- **Psychiatric**
Report depressed mood, suicidal ideations, and suicide attempts.
- **Liver**
There is a potential for elevated liver enzymes or liver dysfunction. Monitor for signs of acute hepatitis or hepatotoxicity. Stopping naltrexone may be necessary.
- **Hypersensitivity**
Allergic reaction or sensitivity to naltrexone.

Warning

Injections site reactions, sometimes are severe and require surgical intervention have been reported primarily in female patients. Increase risk of severe injection reaction occurs if the injection is given subcutaneously rather than intramuscularly.

REMS program by Vivitrol manufacturer to inform patients and health care providers about severe injection site reactions associated with injectable naltrexone.

Cases of overdoses with fatal outcomes have been reported after discontinuing naltrexone treatment and then taking opioids. Individuals are likely to have increased sensitivity to opioids, even at lower doses than had previously been tolerated.

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