

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 12/17/2010

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	Birthdate
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antianxiety Agent (benzodiazepine)	Xanax (alprazolam)	0.25 - 4mg	

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 IV 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.

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

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.

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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 or the United States Pharmacopoeia Dispensing Information (USPDI). 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.

Other Less common side effects include: Accidental injury; bladder pain; bloody or cloudy urine; blurred vision; changes in sexual desire or decreased sexual ability; constipation; cramps; diarrhea; difficult, burning, or painful urination; difficulty in speaking; dizziness or lightheadedness; dryness of mouth or unpleasant taste; fast or pounding heartbeat; frequent urge to urinate; headache; heavy bleeding with menstrual period; inability to have or keep an erection; increased sensitivity of skin to sunlight; increased sweating; itching, redness or other discoloration of skin; loss of appetite; lower back or side pain; nausea or vomiting; pain; severe sunburn; sleepiness or unusual drowsiness; tooth disorder; twitching; weight loss.

Rare side effects include Abnormal thinking, including disorientation, delusions (holding false beliefs that cannot be changed by facts), or loss of sense of reality; agitation; behavior changes, including aggressive behavior, bizarre behavior, decreased inhibition, or outbursts of anger; convulsions (seizures); hallucinations (seeing, hearing, or feeling things that are not there); hypotension (low blood pressure); muscle weakness; skin rash or itching; sore throat, fever, and chills; trouble in sleeping; ulcers or sores in mouth or throat (continuing); uncontrolled movements of body, including the eyes; unusual bleeding or bruising; unusual excitement, nervousness, or irritability; unusual tiredness or weakness (severe); yellow eyes or skin.

For patients taking the short-acting form of this medicine: Take the last dose for each day at least 6 hours before bedtime to help prevent trouble in sleeping

Dependence and Withdrawal Reactions, Including Seizures

Certain adverse clinical events, some life-threatening, are a direct consequence of physical dependence to ALPRAZOLAM. These include a spectrum of withdrawal symptoms; the most important is seizure. Even after relatively short-term use at the doses recommended for the treatment of transient anxiety and anxiety disorder (i.e., 0.75 to 4.0 mg per day), there is some risk of dependence. Spontaneous reporting system data suggest that the risk of dependence and its severity appear to be greater in patients treated with doses greater than 4 mg/day and for long periods (more than 12 weeks). However, in a controlled postmarketing discontinuation study of panic disorder patients, the duration of treatment (3 months compared to 6 months) had no effect on the ability of patients to taper to zero dose. In contrast, patients treated with doses of ALPRAZOLAM greater than 4 mg/day had more difficulty tapering to zero dose than those treated with less than 4 mg/day.

The importance of dose and the risks of ALPRAZOLAM as a treatment for panic disorder

Because the management of panic disorder often requires the use of average daily doses of ALPRAZOLAM above 4 mg, the risk of dependence among panic disorder patients may be higher than that among those treated for less severe anxiety. Experience in randomized placebo-controlled discontinuation studies of patients with panic disorder showed a high rate of rebound and withdrawal symptoms in patients treated with ALPRAZOLAM compared to placebo-treated patients.

Relapse or return of illness was defined as a return of symptoms characteristic of panic disorder (primarily panic attacks) to levels approximately equal to those seen at baseline before active treatment was initiated. Rebound refers to a return of symptoms of panic disorder to a level substantially greater in frequency, or more severe in intensity than seen at baseline. Withdrawal symptoms were identified as those which were generally not characteristic of panic disorder and which occurred for the first time more frequently during discontinuation than at baseline.

In a controlled clinical trial in which 63 patients were randomized to ALPRAZOLAM and where withdrawal symptoms were specifically sought, the following were identified as symptoms of withdrawal: heightened sensory perception, impaired concentration, dysosmia, clouded sensorium, paresthesias, muscle cramps, muscle twitch, diarrhea, blurred vision, appetite decrease, and weight loss. Other symptoms, such as anxiety and insomnia, were frequently seen during discontinuation, but it could not be determined if they were due to return of illness, rebound, or withdrawal.

In two controlled trials of 6 to 8 weeks duration where the ability of patients to discontinue medication was measured, 71%–93% of patients treated with ALPRAZOLAM tapered completely off therapy compared to 89%–96% of placebo-treated patients. In a controlled postmarketing discontinuation study of panic disorder patients, the duration of treatment (3 months compared to 6 months) had no effect on the ability of patients to taper to zero dose.

Seizures attributable to ALPRAZOLAM were seen after drug discontinuance or dose reduction in 8 of 1980 patients with panic disorder or in patients participating in clinical trials where doses of ALPRAZOLAM greater than 4 mg/day for over 3 months were permitted. Five of these cases clearly occurred during abrupt dose reduction, or discontinuation from daily doses of 2 to 10 mg. Three cases occurred in situations where there was not a clear relationship to abrupt dose reduction or discontinuation. In one instance, seizure occurred after discontinuation from a single dose of 1 mg after tapering at a rate of 1 mg every 3 days from 6 mg daily. In two other instances, the relationship to taper is indeterminate; in both of these cases the patients had been receiving doses of 3 mg daily prior to seizure. The duration of use in the above 8 cases ranged from 4 to 22 weeks. There have been occasional voluntary reports of patients developing seizures while apparently tapering gradually from ALPRAZOLAM. The risk of seizure seems to be greatest 24–72 hours after discontinuation.

See PDR, USPDI or US Hospital Formulary Service for all-inclusive list of side effects.

Client Initial _____ Date _____

Medication : Xanax - (alprazolam)

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 ss. 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, which 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
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____