

INFORMED CONSENT FOR MEDICATION

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
Anticonvulsant/ central nervous system agent	Trileptal® (oxcarbazepine)	300 mg - 2400 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.

- ☐ 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 restraint
- ☐ 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.

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 weight increased, abdominal pain, nausea, vomiting, abnormal gait, ataxia, dizziness, headache, somnolence, tremor, abnormal vision, diplopia, nystagmus, fatigue, hyponatremia

Less Common Side Effects indigestion, impairment of balance, purpuric disorder, rash, diarrhea, gastritis, loss of appetite, sense of taste altered

Rare Side Effects anaphylactic reaction, angiodema

Caution

Precautions:

Dermatologic: Serious dermatological reactions (ie, Stevens-Johnson syndrome and toxic epidermal necrolysis), which may be life-threatening or fatal, have occurred and recurred on rechallenge; discontinue use. Increased risk of Stevens-Johnson syndrome and toxic epidermal necrolysis in patients with the HLA-B*1502 allele (most common in Chinese, Thai, Filipino, Malaysian, Korean, and eastern Indian populations); test at-risk patients for HLA-B*1502 and, if present, avoid use, unless benefits clearly outweigh risks.

Endocrine and metabolic: Clinically significant hyponatremia and SIADH may occur, especially during the first 3 months of therapy but also more than 1 year after therapy initiation; monitoring recommended; dose interruption or discontinuation may be necessary. Decreases in T4 may occur without decreases in T3 or TSH.

Hematologic: Hematological reactions, including pancytopenia, agranulocytosis, and leukopenia have been reported; discontinue use.

Hepatic: Use of extended-release tablets is not recommended in patients with severe hepatic impairment; caution is advised with use of immediate-release formulations.

Immunologic: Anaphylaxis and angioedema of the larynx, glottis, lips, and eyelids have been reported with fatalities; immediate and permanent discontinuation recommended. Drug reaction with eosinophilia and systemic symptoms (DRESS) or multiorgan hypersensitivity reactions, some life-threatening or requiring hospitalization, have occurred; discontinue use immediately if suspected. Avoid rapid withdrawal as this may increase seizure frequency and risk for status epilepticus; rapid discontinuation may be considered if withdrawal is needed due to a serious adverse event.

Neurologic: New onset or exacerbation of primary generalized seizures has been reported, especially in pediatric patients; discontinue if occurs.

Psychiatric: Suicidal behavior and ideation may occur with the use of antiepileptic drugs, including oxcarbazepine; monitoring recommended.

Reproductive: Therapy may render hormonal contraceptives less effective; additional non-hormonal forms of contraception are recommended (extended-release).

Special populations (Beers Criteria): Use caution in elderly patients as SIADH or hyponatremia may occur or be exacerbated, and monitor sodium levels when starting or changing doses. Avoid use in elderly patients with history of falls or fractures as syncope, impaired psychomotor function or ataxia may occur (unless used for seizure or mood disorders). Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls.

Pregnancy: Plasma concentrations of the active metabolite of oxcarbazepine may gradually decrease throughout pregnancy and increase following delivery; monitoring is recommended during pregnancy and the postpartum period.

Warning

Syndrome Note Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Steven-Johnson syndrome (SJS) have been reported.

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