

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 05/27/2021

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
Anticonvulsant Migraine Headache Prevention	Topamax (topiramate)	25 mg – 400 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.

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

Abnormal sodium bicarbonate lab values and ammonia levels (metabolic acidosis), confusion, impaired psychomotor performance, memory impairment, mood disorder, feeling nervous, tired, loss of appetite, weight decrease, and change in taste or tingling of the tongue.

Less Common Side Effects

Infectious disease, fever, increased body temperature, reduced concentration span, and fatigue.

Rare Side Effects

Liver failure, drug induced encephalopathy, suicidal thoughts, kidney stones, and withdrawal symptom.

Check with your doctor:

Check with your doctor as soon as possible if any of the following side effects occur:

- Any vision problems, especially blurred vision, double vision, eye pain or rapidly decreasing vision uncontrolled back-and-forth or rolling eye movements, eye redness or irritation, increased eye pressure, or eye pain;
- burning, prickling, or tingling sensations;
- clumsiness or unsteadiness; confusion; continuous, dizziness; drowsiness; generalized slowing of mental and physical activity; memory problems; nervousness, trouble in concentrating or paying attention; unusual tiredness or weakness.
- menstrual changes; menstrual pain; nervousness; speech or language problems;
- back pain; chest pain; constipation; heartburn; hot flushes; increased sweating; leg pain or swelling;
- skin rash; itching; trouble breathing;
- blood in urine; loss of bladder control; decrease in sexual performance or desire; difficult or painful urination; frequent urination; lower back or side pain;
- hearing loss; ringing or buzzing in ears.

Caution

- **Drowsiness/ Older patient with history of falls or fractures**
Avoid activities requiring mental alertness and coordination until you know how this medication affects you. This medication may cause some people to feel unsteady or clumsy. It may cause trouble thinking clearly or cause tiredness, confusion, and drowsiness.
- **Endocrine and Metabolic**
Report symptoms of metabolic acidosis, hyperthermia, and the inability to sweat. These medicines may make you sweat less, causing your body temperature to increase. Use extra care not to become overheated during exercise or hot weather while you are taking this medicine, since overheating may result in heat stroke. Also, hot baths or saunas may make you dizzy or faint while you are taking this medicine.
- **Neurologic**
Do not discontinue the medication abruptly as it may increase seizure activity. Report new or worsening depression, suicidal thoughts or behavior, or changes in mood or behavior.
- **Eyes**
Immediately report changes in vision, eye pain, blurred vision, or decreased visual acuity.
- **Kidneys**
Maintain adequate fluid intake to minimize the risk of kidney stones. It is important that you drink plenty of fluids every day during therapy with topiramate to help prevent kidney stones from forming.
- **Pregnancy/Oral Contraceptives**
This medication may cause fetal harm. The recommendation is to use contraceptives. This medication may decrease the effectiveness of estrogen containing birth control. You should use a different or additional means of birth control while you are using topiramate.
- **Skin Reaction**
Rare but serious allergic reactions such as a body rash, Stevens-Johnson syndrome, or toxic epidermal necrolysis may occur. Report any signs of skin irritation or rash immediately to your prescriber.

Contraindications

- Avoid recent alcohol use within 6 hours before or after topiramate use
- Metformin with topiramate poses an increased risk of metabolic acidosis

Warning

TOPAMAX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Metabolic Acidosis: Hyperchloremic, non-anion gap, metabolic acidosis (i.e., decreased serum bicarbonate below the normal reference range in the absence of chronic respiratory alkalosis) is associated with topiramate treatment. Such electrolyte imbalance has been observed with the use of topiramate in placebo-controlled clinical trials and in the post-marketing period. Generally, topiramate-induced metabolic acidosis occurs early in treatment although cases can occur at any time during treatment.

Some manifestations of acute or chronic metabolic acidosis may include hyperventilation, nonspecific symptoms such as fatigue and anorexia, or more severe sequelae including cardiac arrhythmias or stupor. Chronic, untreated metabolic acidosis may increase the risk for nephrolithiasis or nephrocalcinosis, and may also result in osteomalacia (referred to as rickets in pediatric patients) and/or osteoporosis with an increased risk for fractures. Chronic metabolic acidosis in pediatric patients may also reduce growth rates. A reduction in growth rate may eventually decrease the maximal height achieved.

Measurement of baseline and periodic serum bicarbonate during topiramate treatment is recommended. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing topiramate (using dose tapering). If the decision is made to continue patients on topiramate in the face of persistent acidosis, alkali treatment should be considered.

Acute Myopia and Secondary Angle Closure Glaucoma: A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving topiramate. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness) and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating topiramate therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of topiramate as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of topiramate, may be helpful. Elevated intraocular pressure of any etiology, if left untreated, can lead to serious sequelae including permanent vision loss.

Oligohidrosis and Hyperthermia: Oligohidrosis (decreased sweating), infrequently resulting in hospitalization, has been reported in association with topiramate use. Decreased sweating and an elevation in body temperature above normal characterized these cases. Some of the cases were reported after exposure to elevated environmental temperatures. The majority of the reports have been in children. Patients, especially pediatric patients, treated with topiramate should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Caution should be used when topiramate is prescribed with other drugs that predispose patients to heat-related disorders; these drugs include, but are not limited to, other carbonic anhydrase inhibitors and drugs with anticholinergic activity.

Withdrawal of AEDs: In patients with or without a history of seizures or epilepsy, antiepileptic drugs including topiramate should be gradually withdrawn to minimize the potential for seizures or increased seizure frequency. In situations where rapid withdrawal of topiramate is medically required, appropriate monitoring is recommended.

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