

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	Depakene® (valproic acid)	Initial, 10 to 15 mg/kg/day with a maximum dose of 60 mg/kg/day	

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

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:** Alopecia, increased appetite, weight gain, abdominal pain, diarrhea, indigestion, loss of appetite, nausea, vomiting, asthenia, amnesia, ataxia, dizziness, headache, insomnia, somnolence, tremor, diplopia, amblyopia, blurred vision, feeling nervous, respiratory tract infection, influenza, dose-related thrombocytopenia

**Less Common Side Effects:** Peripheral edema, rash, constipation, ecchymosis, backache, nystagmus, tinnitus, depression, disturbance in thinking, mood swings, bronchitis, dyspnea, pharyngitis, rhinitis, fever, palpitations, tachycardia, hyperammonemia, hematemesis, ototoxicity - deafness, myelodysplastic syndrome

**Rare Side Effects:** Pleural effusion, coma, hyperammonemia-induced encephalopathy, hyperammonemic encephalopathy, tubulointerstitial nephritis, hypersensitivity reaction

**Caution:** Precautions: Do not discontinue without consulting with your doctor. May precipitate life-threatening status epilepticus with attendant hypoxia.

Let the prescriber know if you are using any antibiotics as concomitant use with carbapenem antibiotics (eg, ertapenem, imipenem, meropenem) may lead to loss of seizure control.

- **Endocrine and metabolic:** Hyperammonemia, has been reported and may be present regardless of liver function test results; monitoring recommended and consider discontinuation for persistent ammonia elevations. Hyperammonemic encephalopathy, some cases fatal, have been reported among patients with urea cycle disorders; evaluate for urea cycle disorders prior to initiating therapy in at-risk patients or patients with signs or symptoms of urea cycle disorders; discontinue if condition occurs. Hypothermia, with and without hyperammonemia, has been reported; consider discontinuing therapy if condition occurs.
- **Hematologic:** Dose-related thrombocytopenia, myelodysplasia, decreases in other cell lines, and abnormal coagulation have been reported; baseline assessment and ongoing monitoring recommended (especially during pregnancy or before planned surgery); dose adjustment or discontinuation may be required.
- Increased risk of elevated liver enzymes and thrombocytopenia.
- **Immunologic:** Life-threatening or fatal Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) multiorgan hypersensitivity reactions have been reported; discontinue if suspected and do not resume if an alternative etiology for the signs or symptoms cannot be established. Stimulation of HIV and CMV virus replication may occur.
- **Psychiatric:** Suicidal thoughts and behavior have been reported.
- **Reproductive:** The risks and benefits of valproate use in girls at the onset of puberty needs to be evaluated before initiation of therapy.
- **Special populations:** Elderly require dosage reduction and slower titration due to a greater sensitivity to somnolence; monitoring for excessive somnolence, reduced nutritional intake and weight loss recommended; discontinuation may be required.
- **Special populations (Beers Criteria):** Avoid use in elderly patients with a history of falls or fractures (unless used for seizure or mood disorders) and unless safer alternatives are not available as syncope, impaired psychomotor function, or ataxia may occur. Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls.
- **Special populations (KIDs List):** Avoid use in infants and use caution in children younger than 6 years due to risk of pancreatitis and fatal hepatotoxicity.

**Warning: Black box warning:**

**a) Oral (Capsule, Delayed Release)**

• **Hepatotoxicity**

- General Population: Hepatic failure resulting in fatalities has occurred in patients receiving valproate and its derivatives. These incidents usually have occurred during the first 6 months of treatment. Serious or fatal hepatotoxicity may be preceded by non-specific symptoms such as malaise, weakness, lethargy, facial edema, anorexia, and vomiting. In patients with epilepsy, a loss of seizure control may also occur. Patients should be monitored closely for appearance of these symptoms. Serum liver tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first six months.
- Children under the age of 2 years are at a considerably increased risk of developing fatal hepatotoxicity, especially those on multiple anticonvulsants, those with congenital metabolic disorders, those with severe seizure disorders accompanied by mental retardation, and those with organic brain disease. When valproic acid is used in this patient group, it should be used with extreme caution and as a sole agent. The benefits of therapy should be weighed against the risks. The incidence of fatal hepatotoxicity decreases considerably in progressively older patient groups.
- Patients with Mitochondrial Disease: There is an increased risk of valproate-induced acute liver failure and resultant deaths in patients with hereditary neurometabolic syndromes caused by DNA mutations of the mitochondrial DNA Polymerase gamma (POLG) gene (e.g., Alpers Huttenlocher Syndrome). Valproate is contraindicated in patients known to have mitochondrial disorders caused by POLG mutations and children under 2 years of age who are clinically suspected of having a mitochondrial disorder. In patients over 2 years of age who are clinically suspected of having a hereditary mitochondrial disease, valproic acid should only be used after other anticonvulsants have failed. This older group of patients should be closely monitored during treatment with valproic acid for the development of acute liver injury with regular clinical assessments and serum liver testing. POLG mutation screening should be performed in accordance with current clinical practice. These incidents usually have occurred during the first 6 months of treatment. Serious or fatal hepatotoxicity may be preceded by nonspecific symptoms such as malaise, weakness, lethargy, facial edema, anorexia, and vomiting. In patients with epilepsy, a loss of seizure control may also occur. Patients should be monitored closely for appearance of these symptoms. Liver function tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first 6 months.

• **Fetal Risk**

Valproate can cause major congenital malformations, particularly neural tube defects (eg, spina bifida). In addition, valproate can cause decreased IQ scores and neurodevelopmental disorders following in utero exposure.

Valproate is therefore contraindicated for prophylaxis of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception. Valproate should not be used to treat women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant unless other medications have failed to provide adequate symptom control or are otherwise unacceptable.

Valproate should not be administered to a woman of childbearing potential unless other medications have failed to provide adequate symptom control or are otherwise unacceptable. In such situations, effective contraception should be used.

• **Pancreatitis**

Cases of life-threatening pancreatitis have been reported in both children and adults receiving valproate. Some of the cases have been described as hemorrhagic with a rapid progression from initial symptoms to death. Cases have been reported shortly after initial use as well as after several years of use. Patients and guardians should be warned that abdominal pain, nausea, vomiting and/or anorexia can be symptoms of pancreatitis that require prompt medical evaluation. If pancreatitis is diagnosed, valproate should ordinarily be discontinued. Alternative treatment for the underlying medical condition should be initiated as clinically indicated.

**b) Oral (capsule, liquid filled; syrup)**

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**Syndrome Note:** This medication can cause myelodysplastic syndrome.

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