

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, Antimigraine, Mood Stabilizer	Depakote®; Depakote® ER; Depakote® Sprinkle Capsules (divalproex)	(Delayed-release sprinkle capsule, delayed-release tablet, or extended-release tablet: Initial 10-15 mg/kg/day orally 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.

- | | |
|---|---|
| <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.

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: Abdominal pain, diarrhea, indigestion, loss of appetite, nausea, vomiting, amblyopia, blurred vision, diplopia, infection, influenza, dose-related thrombocytopenia

Less Common Side Effects: Backache, asthenia, dizziness, feeling nervous, headache, insomnia, somnolence, tremor, palpitations, tachycardia, hyperammonemia, pancreatitis, liver failure, ototoxicity - deafness

Rare Side Effects: Drug reaction with eosinophilia and systemic symptoms, hyperammonemic encephalopathy, tubulointerstitial nephritis

Caution:

Precautions: Let the prescriber know if you are using any antibiotics as concomitant use with carbapenem antibiotics may lead to loss of seizure control.

Higher doses are associated with increased risk of liver enzyme elevations and thrombocytopenia.

Do not stop taking the medication without consulting with the doctor. Abrupt discontinuation in epileptic patients may precipitate life-threatening status epilepticus with attendant hypoxia.

- **Endocrine and metabolic**
Hyperammonemia has been reported and may be present regardless of liver function test results. 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. Hypothermia, with and without hyperammonemia, has been reported.
- **Gastrointestinal**
Medication residue may rarely deposit in the stool, sometimes accompanied by diarrhea.
- **Geriatric use**
Elderly require dosage reduction and slower titration due to greater sensitivity to somnolence. Report to the provider in case of excessive somnolence, reduced nutritional intake and weight loss.
- Dose-related thrombocytopenia, myelodysplasia, and abnormal coagulation have been reported; Let your doctor know if you are planning or are pregnant or before planned surgery.
- **Immunologic**
Life-threatening or fatal Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) multiorgan hypersensitivity reactions have been reported; discontinue use if suspected. Stimulation of HIV and CMV virus replication may occur with use.
- **Psychiatric**
Suicidal thoughts and behavior may occur.
- **Special populations (Beers Criteria)**
Avoid use in patients with history of falls or fractures, unless used for seizure or mood disorders, 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.
- **KIDs List**
Avoid use in infants and use caution in children younger than 6 years due to risk of pancreatitis and fatal hepatotoxicity.

Warning:

- **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 six 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 two years are at a considerably increased risk of 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 divalproex sodium 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). Divalproex sodium is contraindicated in patients known to have mitochondrial disorders caused by POLG mutations and children under two years of age who are clinically suspected of having a mitochondrial disorder. In patients over two years of age who are clinically suspected of having a hereditary mitochondrial disease, divalproex sodium should only be used after other anticonvulsants have failed. This older group of patients should be closely monitored during treatment with divalproex sodium 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.

- **Fetal Risk**

Valproate can cause major congenital malformations, particularly neural tube defects (e.g., 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.

Syndrome Note:

Stevens-Johnson syndrome: Stevens-Johnson syndrome has been reported with valproate use.

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