

**INFORMED CONSENT FOR MEDICATION**

**Dosage and / or Side Effect information last revised on 06/08/2017**

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	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 / Mood Stabilizing Agent	Depakene; Depakote; Depakote DR; Depakote ER; Depakote Sprinkles (valproic acid)	125mg – 4000mg (Dose according to blood level)	

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 "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.

Medication: Depakene; Depakote;  
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 Depakote Sprinkles - (valproic acid)

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**

The most common side effects include abdominal or stomach cramps (mild); change in menstrual periods; diarrhea; hair loss; indigestion; loss of appetite; nausea and vomiting; trembling of hands and arms; unusual weight loss or gain.

Check with your doctor as soon as possible if the following occurs: Body aches or pain; congestion; cough; dryness or soreness of throat; fever; hoarseness; runny nose; tender, swollen glands in neck; trouble in swallowing; voice changes.

#### **Less Common Side Effects**

Check with your doctor as soon as possible if these less common side effects occur: abdominal or stomach cramps (severe); behavioral, mood, or mental changes; blurred vision; confusion; continuous, uncontrolled back-and-forth and/or rolling eye movements; dizziness; double vision; earache; faintness, or light-headedness when getting up from a lying or sitting position suddenly; fast, irregular, pounding, or racing heartbeat or pulse; heavy, non-menstrual vaginal bleeding; increase in seizures; loss of appetite; nausea or vomiting (continuing); rapid weight gain; redness or swelling in ear; spots before eyes; sweating; swelling of face, arms, hands, lower legs, or feet; tingling of hands or feet; tiredness and weakness; unusual bleeding or bruising; unusual tiredness or weakness; unusual weight gain or loss; vomiting of blood or material that looks like coffee ground; yellow eyes or skin.

#### **Rare Side Effects**

Rare side effects include clumsiness or unsteadiness; constipation; dizziness; drowsiness; headache; skin rash; unusual excitement, restlessness, or irritability

#### **Warning**

#### **Black Box Warning:**

#### **Hepatotoxicity**

Hepatic failure resulting in fatalities has occurred in patients receiving valproic acid and its derivatives. Experience has indicated that children under the age of 2 years are at a considerable 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 this drug 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. Above this age group, experience in epilepsy has indicated that the incidence of fatal hepatotoxicity decreases considerably in progressively older patient groups. 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 the appearance of these symptoms. Liver function tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first six months.

#### **Teratogenicity**

Valproate can produce teratogenic effects such as neural tube defects (e.g., spina bifida). Accordingly, the use of valproate products in women of childbearing potential requires that the benefits of its use be weighed against the risk of injury to the fetus. This is especially important when the treatment of a spontaneously reversible condition not ordinarily associated with permanent injury or risk of death (e.g., migraine) is contemplated.

#### **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 conditions should be initiated as clinically indicated.

#### **MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA**

—Hepatotoxicity: Assess symptoms and LFTs at baseline and frequent intervals, especially within first 6 months.

—Pancreatitis: Patients should be informed of warning signs.

See PDR for an all-inclusive list of side effects.

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**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