

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 |
|---------------------|--------------------|--|--------------------------|
| Sedative/ Hypnotic  | Sonata® (zaleplon) | Adults: 5 mg - 20 mg immediately before bedtime<br>Children up to 18 years of age: Use and dose must be determined by doctor |                          |

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:**


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**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.

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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.
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Continued – Possible side effects, warnings, and cautions associated with this medication.

**Most Common Side Effects** dizziness, headache

**Less Common Side Effects** abdominal pain, paresthesia, pain in eye, dysmenorrhea, depression, peripheral edema, photosensitivity, pruritus, rash, colitis, loss of appetite, nausea, sense of smell altered, arthritis, myalgia, amnesia, asthenia, confusion, hypoesthesia, increased muscle tone, migraine, somnolence, tremor, abnormal vision, conjunctivitis, hyperacusis, otalgia, depersonalization, hallucinations, bleeding from nose, bronchitis, arthralgia

**Rare Side Effects** angioedema

**Caution****Precautions:**

**Administration:** Due to rapid onset of action, only ingest once in bed. Rapid dose decrease or abrupt discontinuation has caused withdrawal symptoms with the use of sedative/hypnotics.

**Comorbidities:** Use cautiously in patients with diseases or conditions that could affect metabolism or hemodynamic responses.

**Concomitant use:** Concomitant use with other sedative-hypnotics at bedtime or the middle of the night is not recommended. Coadministration between medication-assisted treatment (MAT) drugs (eg, methadone and buprenorphine) and benzodiazepines or other CNS depressants (including alcohol) may increase the possibility of harm, including overdose and death, however, concomitant therapy with MAT may be appropriate in some patients; if concomitant use is necessary, careful management and monitoring recommended. Do not take with alcohol.

**Fall risk:** Due to drowsiness and decreased level of consciousness, patients (especially elderly) are at an increased risk of falls.

**Hepatic:** Use not recommended in patients with severe hepatic impairment; dose reduction required with mild or moderate impairment.

**Immunologic:** Sonata® contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in susceptible persons; increased incidence in patients with aspirin hypersensitivity.

**Immunologic:** Rare cases of angioedema involving the tongue, glottis or larynx and anaphylaxis (dyspnea, throat closing, or nausea and vomiting) have been reported in patients after taking the first or subsequent doses; may be fatal; do not rechallenge after angioedema. Symptoms suggestive of anaphylaxis (eg, dyspnea, throat closing, or nausea and vomiting) have been reported.

**Neurologic:** CNS depressant; additive effects may occur with other CNS depressant agents including, psychotropic medications, anticonvulsants, antihistamines, narcotic analgesics, anesthetics; dose adjustment may be needed. Other complex sleep behaviors (eg, preparing and eating food, making phone calls, or having sex) have been reported with and without use of alcohol and other CNS depressants, and patients usually do not remember these events; immediate discontinuation may be necessary. Increased risk of next-day psychomotor impairment, including impaired driving, if taken with less than a full night sleep remaining (7 to 8 hours), if higher than recommended dose is taken, if co-administered with other CNS depressants or alcohol, or if co-administered with other drugs that increase blood levels of zaleplon. Worsening of insomnia or unremitting insomnia despite 7 to 10 days of treatment may be unrecognized psychiatric or physical disorder; evaluation required.

**Psychiatric:** Emergence of new thinking or behavior abnormalities may be unrecognized psychiatric or physical disorder; evaluation required. Patients with signs or symptoms of depression may present with suicidal tendencies; intentional overdose is more common; prescribe the least amount of drug at any 1 time.

**Respiratory:** May depress respiratory drive, especially in patients with compromised respiratory function; monitoring recommended in patients with compromised respiration due to preexisting illness.

Special populations (Beers Criteria): Avoid use in older adults as there is minimal improvement in sleep latency and duration but with adverse effects similar to benzodiazepines (eg, delirium, dementia, cognitive impairment, falls, fractures), increased emergency visits, hospitalization, and motor vehicle crashes. Avoid use in older adults with or at high risk of delirium, in patients with dementia or cognitive impairment, and in elderly with a history of falls or fractures (unless safer alternatives are not available), due to the potential of inducing or worsening delirium, risk of adverse central nervous system effects, and the risk of ataxia, impaired psychomotor function, syncope, and additional falls. Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of falls and fractures. Elderly or debilitated patients may have greater sensitivity to impaired motor and/or cognitive performance after repeated exposure; monitoring and dose reduction recommended.

### Warning

Black Box Warning:

Oral (Capsule)-

Complex Sleep Behaviors: Complex sleep behaviors including sleep-walking, sleep driving, and engaging in other activities while not fully awake may occur following use of zaleplon. Some of these events may result in serious injuries, including death. Discontinue zaleplon immediately if a patient experiences a complex sleep behavior.

### Syndrome Note

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<br><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<br><input type="checkbox"/> Yes <input type="checkbox"/> No |
| Obtained from – PRINT – Parent / Guardian (POA-HC) Name | Date Expires  | Date Received  |