|  |  |
| --- | --- |
| DEPARTMENT OF HEALTH SERVICESDivision of Care and Treatment ServicesF-24277 (05/2024) | STATE OF WISCONSIN42 CFR483.420(a)(2)DHS 134.31(3)(o)DHS 94.03 & 94.09§§ 51.61(1)(g) & (h) |

|  |
| --- |
| INFORMED CONSENT FOR MEDICATIONDosage and / or Side Effect information last revised on 04/16/2021Completion 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 bedtimeChildren 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:       |
| 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. |

See Page 2

| F-24277  | Medication: Sonata - (zaleplon) |
| --- | --- |
| 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: headache; dizziness; muscle weakness; nausea. |
| **Less Common Side Effects:** chest pain; swelling of the arms, legs, ankles, or feet; drowsiness; forgetfulness; tingling of the hand, feet, or face; altered sense of smell; depersonalization; decreased sense of touch; malaise; changes in hearing; abnormal thinking; anxiety; depression; migraine; nervousness; hallucinations; vertigo; itchy skin; skin rash; increased skin sensitivity to the sun; abdominal pain; anorexia; constipation; changes with taste; regurgitation of stomach acid or acidic taste in the mouth; dry mouth; stomach upset; painful menstruation; tremor; back or joint pain; muscle pain; eye pain; change in vision; eye infection; earache.  |
| **Rare Side Effects**: abnormal walk; abnormal menstrual bleeding; acne; agitation; hair loss; chest pain; abnormal, stiff, or uncontrollable movements of the fingers; bladder pain; grinding teeth; joint pain; chills; yellowing of the eyes or skin; confusion; rash; loss of hearing; lips or skin turning blue; decreased sexual function or desire; excessive sweating; double vision; dry eyes; difficulty speaking or swallowing; ;eczema; swelling of the throat, lips, tongue, face, arms or legs; emotional changes; euphoria; facial paralysis; gas; bleeding of the gums; glaucoma; gout; hangover effect; severe bleeding; hiccups; hostility; hyperglycemia (high blood sugars); hypertension (high blood pressure); hyperventilation; hypoglycemia (low blood sugars); hypotension (low blood pressure); hypothyroidism; impaired consciousness; unable to obtain or maintain an erection; increased appetite; increased thirst; insomnia (difficulty falling asleep or staying asleep; neck stiffness; nerve pain; nightmares; orthostatic hypotension (dizziness when standing from a seated or lying position; palpitations; fear of light; slurred speech; snoring; fainting; fast heartbeat; tinnitus (ringing of the ears); tongue discoloration; increased urinary frequency; watery eyes; weight gain; or loss; dry or flaky skin.  |
| **Caution*** **Behavior changes**

This medicine may cause some people to feel a false sense of well-being, experience hallucinations, aggression, bizarre behavior, or depersonalization. People may also experience forgetfulness. * **Driving and operating heavy machinery**

This medication may cause people to become drowsy, dizzy, or less alert than they are normally. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not fully alert.* **Depression**

Use with caution in patients with depression; worsening of depression, including suicide or suicidal ideation, has been reported with the use of hypnotics. If you do experience this, please call your doctor as soon as possible.  |
| **Warning: [Black Box Warning]: Complex sleep behaviors:** Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including zaleplon. Because some of the important adverse effects of zaleplon appear to be dose-related, it is important to use the lowest possible effective dose, especially in the elderly. A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bizarre behavior, agitation, hallucinations, and depersonalization. Amnesia and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of sedative/hypnotics. It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.Following rapid dose decrease or abrupt discontinuation of the use of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs. Zaleplon, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, zaleplon should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving zaleplon should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (e.g., operating machinery or driving a motor vehicle) after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of zaleplon. Zaleplon, as well as other hypnotics, may produce additive CNS depressant effects when co-administered with other psychotropic medications, anticonvulsants, antihistamines, narcotic analgesics, anesthetics, ethanol, and other drugs that themselves produce CNS depression. Zaleplon should not be taken with alcohol. Dosage adjustment may be necessary when zaleplon is administered with other CNS-depressant agents because of the potentially additive effects. |
| 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 [ ]  Self[ ]  Parent [ ]  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[ ]  Yes [ ]  No |
| Obtained from – PRINT – Parent / Guardian (POA-HC) Name | Date Expires | Date Received |