

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/21/2020

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	Rozerem (ramelteon)	Adults: 8 mg at bedtime	

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.

See Page 2

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: dizziness; sleepiness or unusual drowsiness.

Less Common Side Effects: body aches or pain; change in taste; worsening insomnia (worsening ability to fall asleep or stay asleep); depression; nausea; upset stomach; increased risk of upper respiratory tract infections (cough, congested airways, fatigue, fever); increased risk of influenza (fever, chills, body aches, severe cough, headaches).

Rare Side Effects: swelling of the face, tongue, or throat; development of generalized rash; complex sleep behaviors (sleep-driving, cooking or eating food, making phone calls, engaging in sexual behavior) without remembering the event the next morning; decreased levels of testosterone.

Caution

- **Take medication as you are getting into bed**
Take ramelteon just before going to bed, when you are ready to go to sleep. This medicine works very quickly to put you to sleep.
- **Driving and operating heavy machinery**
Do not drive, operate heavy machinery, or participate in any other activity that could be hazardous if not fully alert while on this medication. This medication is for sleep, and will make participating in these activities very dangerous. Be cautious about participating in these activities upon waking as you may still be groggy from the medication.
- **Complex sleep behaviors**
An increased risk for hazardous sleep-related activities such as sleep-driving, cooking and eating food, having sex, and making phone calls while asleep have been noted; forgetting what happened, anxiety, and other neuropsychiatric symptoms may also occur. The use of alcohol, other CNS depressants, and exceeding the recommended maximum dose may increase the risk of these activities. Discontinue treatment and report any complex sleep behavior.
- **Ramelteon and clinical mental depression**
Use with caution in patients with depression; worsening of depression, including suicidal ideation has been reported with the use of hypnotics.
- **Reproductive Effects**
Use in Adolescents and Children: Ramelteon has been associated with an effect on reproductive hormones in adults, e.g., decreased testosterone levels and increased prolactin levels. It is not known what effect chronic or even chronic intermittent use of ramelteon may have on the reproductive axis in developing humans.
- **Need to Evaluate for Co-morbid Diagnoses:**
Since 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 cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder and requires further evaluation of the patient. Exacerbation of insomnia and emergence of cognitive and behavioral abnormalities were seen with ramelteon during the clinical development program.

Use in Patients with Concomitant Illness: Ramelteon has not been studied in subjects with severe sleep apnea and is not recommended for use in this population.

Specific Populations: Ramelteon should not be used by patients with severe hepatic impairment.

Warning

Severe Anaphylactic and Anaphylactoid Reactions

Rare cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of ramelteon. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with ramelteon should not be rechallenged with the drug.

Need to Evaluate for Co-morbid Diagnoses

Since 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 cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder and requires further evaluation of the patient. Exacerbation of insomnia and emergence of cognitive and behavioral abnormalities were seen with ramelteon during the clinical development program.

Abnormal Thinking and Behavioral Changes

A variety of cognitive and behavior changes have been reported to occur in association with the use of hypnotics. In primarily depressed patients, worsening of depression (including suicidal ideation and completed suicides) have been reported in association with the use of hypnotics. Hallucinations, as well as behavioral changes such as bizarre behavior, agitation and mania have been reported with ramelteon use. Amnesia, anxiety and other neuro-psychiatric symptoms may also occur unpredictably. Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake after ingestion of a hypnotic) and other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex), with amnesia for the event, have been reported in association with hypnotic use. The use of alcohol and other CNS depressants may increase the risk of such behaviors. These events can occur in hypnotic-naïve as well as in hypnotic-experienced persons. Complex behaviors have been reported with the use of ramelteon. Discontinuation of ramelteon should be strongly considered for patients who report any complex sleep behavior.

CNS Effects

Patients should avoid engaging in hazardous activities that require concentration (such as operating a motor vehicle or heavy machinery) after taking ramelteon. After taking ramelteon, patients should confine their activities to those necessary to prepare for bed.

Patients should be advised not to consume alcohol in combination with ramelteon as alcohol and ramelteon may have additive effects when use in conjunction.

Reproductive Effects**Use in Adolescents and Children**

Ramelteon has been associated with an effect on reproductive hormones in adults, e.g., decreased testosterone levels and increased prolactin levels. It is not known what effect chronic or even chronic intermittent use of ramelteon may have on the reproductive axis in developing humans.

Use in Patients with Concomitant Illness: Ramelteon has not been studied in subjects with severe sleep apnea and is not recommended for use in this population.

Specific Populations: Ramelteon should not be used by patients with severe hepatic impairment.

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