

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 04/16/2021

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
Antipsychotic Agent/Mood	Risperdal Risperdal Consta (risperidone)	Adults: 1 mg-16 mg daily Older adults: 1 mg daily Consta injection: 25 mg-50 mg IM every 2 weeks Children under the age of 18 years as determined by prescriber: 1-6 mg	

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:

Client Initial _____ Date _____

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

Medication : Risperdal;
Risperdal Consta - (risperidone)

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: constipation; coughing; drowsiness; headache; increased dream activity; nausea; increased appetite; upper abdominal pain; sleepiness or unusual drowsiness; sore throat; stuffy or runny nose; unusual tiredness or weakness; weight gain; muscle spasms of face, neck, and back; twisting movements of body; anxiety or nervousness; changes in vision, including blurred vision loss of balance control; mask-like face; problems in urination or increase in amount of urine; restlessness or need to keep moving (severe); shuffling walk; stiffness or weakness of arms or legs; tic-like or twitching movements; trembling and shaking of fingers and hands; trouble in sleeping.

Less Common Side Effects: diarrhea; dry mouth; heartburn; mood or mental changes, including aggressive behavior, agitation, difficulty in concentration, and memory problems; skin rash or itching; sudden weakness or numbness in the face, arms or legs; unusual secretion of milk/elevated prolactin levels; decreased sexual desire or performance; inability to move eyes; back pain; body aches or pain; chills; menstrual changes; dandruff; darkening of skin color; dry skin; ear congestion; fever; increase in controllable and uncontrollable body movements; increased sensitivity of the skin to sun; increased watering of mouth; joint pain; loss of voice; oily skin; pain or tenderness around eyes and cheekbones; shortness of breath or troubled breathing; sneezing; stomach pain; toothache; tightness of chest or wheezing; vomiting; weight loss; difficulty walking; falling; eye infection; increased risk of upper respiratory tract infections; development of breasts in males; increased blood sugars; increased thirst; pounding or abnormal heartbeat.

Rare Side Effects: Although rare, contact you doctor as soon as possible if any of the following side effects occur: convulsions (seizures); difficult or fast breathing; fast heartbeat or irregular pulse; fever (high); high or low blood pressure; greatly increased sweating; loss of bladder control; muscle stiffness (severe); unusually pale skin; unusual tiredness or weakness (severe); difficulty in speaking or swallowing; high body temperature (dizziness; fast, shallow breathing; fast, weak heartbeat; headache; muscle cramps; pale, clammy skin; increased thirst); lip smacking or puckering; low body temperature (confusion, drowsiness, poor coordination, shivering); prolonged, painful, inappropriate erection of the penis; puffing of cheeks; rapid or worm-like movements of tongue; uncontrolled chewing movements; uncontrolled movements of arms and legs; extreme thirst; increased blinking or spasms of eyelid; loss of appetite; talking, feeling, and acting with excitement and activity that cannot be controlled; uncontrolled twisting movements of neck, trunk, arms, or legs; unusual bleeding or bruising; unusual facial expressions or body positions.

Caution

- **Extrapyramidal symptoms (EPS)**
Patients have reported muscle spasms of the neck and back; shuffling walk; tic-like (jerky) movements of the head, face and neck; trembling and shaking of the hands and fingers; inability to move eyes; mask-like face; loss of balance control; blurred vision; difficulty speaking or swallowing. Additionally, though not common, Tardive Dyskinesia has been reported. Tardive Dyskinesia presents with lip smacking or puckering, puffing of cheeks, rapid or fine worm-like movement of tongue, uncontrolled chewing movement, or uncontrolled movements of arms and legs may occur and may not go away after stopping use of the medication.
- **Neuroleptic Malignant Syndrome (NMS)**
Use may be associated with NMS. Monitor for changes in thinking, fever, muscle stiffness, and/ autonomic instability (unable to exercise, abnormal sweating, loss of appetite, loss of bladder control, difficulty with ejaculation, blurry vision). Call your doctor as soon as possible if you believe you may have NMS.
- **QT prolongation**
This drug has the potential to prolong the QT interval of the heart. Caution should be exercised by those who have a history of QT prolongation, heart syndromes such as Congenital Long QT Syndrome (CLQTS), or by those who have multiple risk factors for QT prolongation.
- **Driving and operating heavy machinery**
Risperidone may cause drowsiness or dizziness, which could make driving, operating heavy machinery, or participating in other activities requiring alertness dangerous. Be sure you know how this medication affects you before participating in these activities.
- **Blood disorder**
Check with your doctor immediately if you develop fever, chills, sore throat, or sores in the mouth. These may be signs of a very serious blood problem that has occurred rarely in patients taking risperidone. This medication also has the potential to increase bleeding/
- **Orthostatic hypotension**
Orthostatic hypotension is when one feels dizzy while getting up from a lying or sitting position. Getting up slowly may help. If this problem continues or gets worse, check with your doctor.
- **Fall risk**
This medication increases the risk of experiencing a fall due to drowsiness and dizziness. Caution should be exercised by those who have a history of falls.
- **Weight gain**
This medication has been associated with increased appetite and weight gain.
- **Seizure**

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This medication may, in rare cases, cause individuals to experience a seizure. Caution should be exercised in those who have a history of seizures.

- **Suicide**
This medication has the potential to cause new or worsening thoughts of suicide. If you experience these, immediately call your doctor.
- **Withdrawal**
This medication should not be suddenly stopped as it may cause an individual to experience symptoms of withdrawal. Please speak with your physician before stopping this medication.
- **Anticholinergic effects**
May cause symptoms such as confusion, agitation, constipation, dry mouth, blurred vision, or difficulty urinating.

Warning: [Black Box Warning]: Increased Mortality in Elderly Patients with Dementia Related Psychosis: Elderly patients with dementia related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo controlled trials (modal duration of 10 weeks, largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug treated patients of between 1.6 to 1.7 times that seen in placebo treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

This drug is not approved for the treatment of patients with dementia-related psychosis.

See PDR 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
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Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received
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