RISPERIDONE:

Class: Atypical Antipsychotic Agent

Indications: Oral: Treatment of schizophrenia; treatment of acute mania or mixed episodes associated with bipolar I disorder (as monotherapy in children or adults, or in combination with lithium or valproate in adults); treatment of irritability/aggression associated with autistic disorder

Injection: Treatment of schizophrenia; maintenance treatment of bipolar I disorder in adults as monotherapy or in combination with lithium or valproate

Treatment of Tourette's syndrome; psychosis/agitation related to Alzheimer's dementia; post-traumatic stress disorder (PTSD)

Available dosage form in the hospital: TAB (1MD,2MG, 3MG, 4MG), VIAL (25MD, 37.5MG, 50MG), 1MG/ML SOLUTION

Dosage: **Note:** When reinitiating treatment after discontinuation, the initial titration schedule should be followed.

-Bipolar mania: *Oral:* Recommended starting dose: 2-3 mg once daily; if needed, adjust dose by 1 mg daily in intervals ≥24 hours; dosing range: 1-6 mg daily.
Maintenance: No dosing recommendation available for treatment >3 weeks duration

-Bipolar I maintenance: *I.M. (Risperdal® Consta®):* 25 mg every 2 weeks; if unresponsive, some may benefit from larger doses (37.5-50 mg); maximum dose: 50 mg every 2 weeks. Dosage adjustments should not be made more frequently than every 4 weeks. A lower initial dose of 12.5 mg may be appropriate in some patients (eg, demonstrated poor tolerability to other psychotropic medications).
****Note:** Oral risperidone (or other antipsychotic) should be administered with the initial injection of Risperdal® Consta® and continued for 3 weeks (then discontinued) to maintain adequate therapeutic plasma concentrations prior to main release phase of risperidone from injection site. When switching from depot administration to a short-acting formulation, administer short-acting agent in place of the next regularly-scheduled depot injection.

-Schizophrenia:

-*Oral:* Initial: 2 mg daily in 1-2 divided doses; may be increased by 1-2 mg daily at intervals ≥24 hours to a recommended dosage range of 4-8 mg daily; may be given as a single daily dose once maintenance dose is achieved; daily dosages >6 mg do not appear to confer any additional benefit, and the incidence of extrapyramidal symptoms is higher than with lower doses. Further dose adjustments should be made in increments/decrements of 1-2 mg daily on a weekly basis. Dose range studied in clinical trials: 4-16 mg daily. Maintenance: Recommended dosage range: 2-8 mg daily

-*I.M. (Risperdal® Consta®):* Initial: 25 mg every 2 weeks; if unresponsive, some may benefit from larger doses (37.5-50 mg); maximum dose: 50 mg every 2 weeks. Dosage adjustments should not be made more frequently than every 4 weeks. A lower initial dose of 12.5 mg may be appropriate in some patients (eg, demonstrated poor tolerability to other psychotropic medications).
****Note:** Oral risperidone (or other antipsychotic) should be administered with the initial injection of Risperdal® Consta® and continued for 3 weeks (then discontinued) to maintain adequate therapeutic plasma concentrations prior to main release phase of risperidone from injection site. When switching from depot administration to a short-acting formulation, administer short-acting agent in place of the next regularly-scheduled depot injection.

-Post-traumatic stress disorder (PTSD) (unlabeled use): *Oral:* 0.5-8 mg daily (Bandelow, 2008; Benedek, 2009)

-Tourette's syndrome (unlabeled use): *Oral:* Initial: 0.25 mg once daily for 2 days, then 0.25 mg twice daily for 3 days, then 0.5 mg twice daily for 2 days; titrate slowly thereafter in increments/decrements ≤0.5 mg twice daily and at intervals ≥3 days; maximum dose: 6 mg daily (Dion, 2002)

Geriatric

-*Oral:* Initial: 0.5 mg twice daily; titration should progress slowly in increments of no more than 0.5 mg twice daily; increases to dosages >1.5 mg twice daily should occur at intervals of ≥1 week.

****Note:** Additional monitoring of renal function and orthostatic blood pressure may be warranted. If once-a-day dosing in the elderly or debilitated patient is considered, a twice daily regimen should be used to titrate to the target dose, and this dose should be maintained for 2-3 days prior to attempts to switch to a once-daily regimen.

-*Psychosis/agitation related to Alzheimer's dementia (unlabeled use):* Initial: 0.25-1 mg daily; if necessary, gradually increase as tolerated not to exceed 1.5-2 mg daily; doses >1 mg daily are associated with higher rates of extrapyramidal symptoms (Rabins, 2007)

-*I.M. (Risperdal® Consta®):* 25 mg every 2 weeks; a lower initial dose of 12.5 mg may be appropriate in some patients.

****Note:** Oral risperidone (or other antipsychotic) should be administered with the initial injection of Risperdal® Consta® and continued for 3 weeks (then discontinued) to maintain adequate therapeutic plasma concentrations prior to main release phase of risperidone from injection site. When switching from depot administration to a short-acting formulation, administer short-acting agent in place of the next regularly-scheduled depot injection.

Renal Impairment:

-Oral: Cl_{cr} <30 mL/minute: Starting dose of 0.5 mg twice daily; titration should progress slowly in increments of no more than 0.5 mg twice daily; increases to dosages >1.5 mg twice daily should occur at intervals of ≥1 week. Clearance of the active moiety is decreased by 60% in patients with moderate-to-severe renal disease (Cl_{cr} <60 mL/minute) compared to healthy subjects.

-I.M.: Initiate with **oral** dosing (0.5 mg twice daily for 1 week then 2 mg daily for 1 week); if tolerated, begin 25 mg **I.M.** every 2 weeks; continue oral dosing for 3 weeks after the first I.M. injection. An initial I.M. dose of 12.5 mg may also be considered.

Hepatic Impairment:

-Oral: Child-Pugh class C: Starting dose of 0.5 mg twice daily; titration should progress slowly in increments of no more than 0.5 mg twice daily; increases to dosages >1.5 mg twice daily should occur at intervals of ≥1 week. The mean free fraction of risperidone in plasma was increased by 35% in patients with hepatic impairment compared to healthy subjects.

-I.M.: Initiate with **oral** dosing (0.5 mg twice daily for 1 week then 2 mg daily for 1 week); if tolerated, begin 25 mg **I.M.** every 2 weeks; continue oral dosing for 3 weeks after the first I.M. injection. An initial I.M. dose of 12.5 mg may also be considered.

Common side effect:

Central nervous system: Sedation (children 12% to 63%; adults 5% to 11%), parkinsonism (children: 28% to 62%; adults 8% to 25%), somnolence (adults 5% to 41%; children 4% to 11%), insomnia (≤32%), fatigue (children 18% to 31%; adults 1% to 9%), headache (12% to 21%), anxiety (≤8% to 16%), dizziness (3% to 16%), fever (children 16%; adults 1% to 2%), akathisia (5% to 11%)

Gastrointestinal: Appetite increased (children 4% to 44%; adults 4%), weight gain (≥7% kg increase from baseline: children 8% to 33%; adults 4% to 21%), vomiting (children 10% to 20%; adults <4%), constipation (5% to 17%), nausea (5% to 16%), abdominal pain (children 6% to 16%; adults <4%), drooling (children 12%; adults <4%)

Genitourinary: Urinary incontinence (children 5% to 22%; adults <4%), enuresis (children 16%; adults <1%)

Neuromuscular & skeletal: Tremor (adults ≤24%; children ≤11%)
Respiratory: Nasopharyngitis (children 19%; adults ≤4%), cough (children ≤17%; adults ≤4%), rhinorrhea (children 12%; adults <4%)

Pregnancy Risk Factor: C