RISPERIDONE (Risperdal) Fact Sheet [G]

BOTTOM LINE:
Risperidone offers more efficacy and safety data in kids than other antipsychotics and is often used first-line in autistic kids, but you need to expect and monitor for EPS, prolactinemia, and weight gain. Consider co-administration with benztropine to prevent EPS and/or metformin to prevent weight gain.

PEDIATRIC FDA INDICATIONS:
Schizophrenia (13–17 years); **bipolar mania, monotherapy and adjunctive** (10–17 years); **irritability in autism** (5–17 years).

ADULT FDA INDICATIONS:
Schizophrenia; bipolar disorder, manic/mixed.

OFF-LABEL USES:
Bipolar depression; behavioral disturbances; impulse control disorders; Tourette's disorder.

DOSAGE FORMS:
- **Tablets (G):** 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg.
- **Oral solution (G):** 1 mg/mL.
- **Orally disintegrating tablets (Risperdal M-Tab, [G]):** 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg.
- **Long-acting injection (Risperdal Consta):** 12.5 mg, 25 mg, 37.5 mg, 50 mg (see LAI fact sheet and table).
- **Long-acting injection (Perseris):** 90 mg, 120 mg (see LAI fact sheet and table).

PEDIATRIC DOSAGE GUIDANCE:
- Autism (children ≥5 years): If <15 kg (33 lbs), use with caution. For 15–20 kg (33–44 lbs), start 0.25 mg/day, ↑ to 0.5 mg/day after ≥4 days. If response insufficient, may ↑ by 0.25 mg/day in ≥2-week intervals; give QD or BID. For ≥20 kg (44 lbs), start 0.5 mg/day; may ↑ to 1 mg/day after ≥4 days. If response insufficient, may ↑ dose by 0.5 mg/day in ≥2-week intervals; give QD or BID.
- Bipolar mania or schizophrenia (children): Start 0.5 mg QD; ↑ in increments of 0.5–1 mg/day at intervals ≥24 hours to target dose of 2–3 mg/day; doses >3 mg/day do not confer additional benefit and are associated with increased side effects.

MONITORING: Weight, waist circumference, glucose, lipids, BP; prolactin, abnormal movements.

COST: $

SIDE EFFECTS:
- Most common: EPS, somnolence, anxiety, dizziness, salivary hypersecretion, fatigue, prolactin elevation, weight gain, increased appetite.
- Serious but rare: Orthostatic hypotension may occur, particularly at higher doses or with rapid titration. Hyperprolactinemia with clinical symptoms (sexual side effects, galactorrhea, amenorrhea).

MECHANISM, PHARMACOKINETICS, AND DRUG INTERACTIONS:
- Dopamine D2 and serotonin 5HT2A receptor antagonist.
- Metabolized by CYP2D6; t ½: 20 hours.
- CYP2D6 inhibitors (eg, fluoxetine, paroxetine, duloxetine, quinidine) may increase effects of risperidone; reduce risperidone dose. Carbamazepine reduces levels and effects of risperidone; may need to double risperidone dose.

EVIDENCE AND CLINICAL PEARLS:
- Seven published trials have reported efficacy of risperidone in adolescents with schizophrenia (two open label, two comparisons with olanzapine and haloperidol, two comparisons with olanzapine, and one randomized placebo-controlled study).
- A three-week randomized trial in 169 children (ages 10–17) with bipolar mania found significantly higher remission rates with risperidone compared to placebo. A six-week randomized trial in 66 kids (ages 8–18) with bipolar mania found significantly higher remission rates with risperidone compared to divalproex. An eight-week open-label trial in 279 kids (ages 6–15) with bipolar mania found higher response rates with risperidone compared to both lithium and divalproex sodium; responses to lithium vs divalproex were similar.
- In autistic kids, associated irritability as well as symptoms of aggression toward others, deliberate self-injuriousness, temper tantrums, and quickly changing moods are improved.
- In studies with kids, about ⅓ gained more than 7% of body weight, and over 80% had elevations in prolactin (dose related, more frequent in girls than boys).
- Along with paliperidone, causes the most EPS and hyperprolactinemia of all the second-generation antipsychotics.
- When reinitiating after discontinuation, initial titration schedule should be followed.

FUN FACT:
Risperdal M-tabs are marketed in other countries as Risperdal Quicklets.