Commonly observed events associated with RISPERDAL at an incidence of ≥5% and at least 2× placebo: In a monotherapy trial—somnolence, dystonia, akathisia, dyspepsia, nausea, parkinsonism, abnormal vision, saliva increase, and myalgia. In an adjunctive therapy trial with mood stabilizers (lithium and valproate)—somnolence, dizziness, parkinsonism, saliva increase, akathisia, abdominal pain, urinary incontinence, diarrhea, and rhinitis.
Maintenance treatment: While maintenance of initial response and prevention of new manic episodes is desirable, there are no systematically obtained data to support the use of RISPERDAL in longer-term treatment (>3 weeks).
Drug interactions with anticonvulsants and lithium: RISPERDAL drug interactions listed are not all-inclusive. Induction of clearance by carbamazepine can lead to sub-therapeutic levels of the RISPERDAL active moiety (risperidone and 9-hydroxyrisperidone). In a schizophrenia trial, co-administration of carbamazepine and risperidone leads to a 50% reduction in plasma concentrations of the RISPERDAL active moiety. Repeated oral doses of RISPERDAL did not affect the average concentration and exposure (AUC) of valproate; however, there was a 20% increase in peak plasma (C_{max}) concentrations of valproate. Repeated oral doses of RISPERDAL did not affect the exposure (AUC) or peak plasma concentrations (C_{max}) of lithium.

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 01-RS-1384 February 2004

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Help turn lives around with response, remission, and reconnection[1–3]

- Rapidly improved manic symptoms as early as Day 3 without inducing depression*[1]
- Delivered significantly greater remission rates in combination vs mood stabilizer†[3]
- Improvement in symptoms and general functioning†[1]

*MADRS: RISPERDAL was not associated with induction or worsening of depressive symptoms as measured by mean change from baseline to endpoint.

†Three-week trial.

‡As measured by the Young Mania Rating Scale and the Global Assessment Scale.

References: 1. Data on file: RISUSA229 Study (a double-blind, placebo-controlled monotherapy trial). Janssen Pharmaceutica Products, L.P., Titusville, NJ. **2.** Data on file: RIS-BI212. Janssen Pharmaceutica Products, L.P., Titusville, NJ. **3.** Data on file: RISUSA102 Study (a double-blind, placebo-controlled adjunctive therapy trial). Janssen Pharmaceutica Products, L.P., Titusville, NJ.

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