Johnson&Johnson

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24 September 2025

Discontinuation of RISPERDAL® (risperidone) tablets across all strengths as of 15 December 2025

Dear Healthcare Professional,

Janssen-Cilag Pty Ltd (**Janssen**), a Johnson and Johnson company, would like to inform you of the discontinuation of RISPERDAL® (risperidone) tablet formulation across all strengths in New Zealand as of 15 December 2025 for:

- RISPERDAL® risperidone 0.5mg 20 tablets: TT50-5241g
- RISPERDAL® risperidone 1mg 60 tablets: TT50-5241
- RISPERDAL® risperidone 2mg 60 tablets: TT50-5241b
- RISPERDAL® risperidone 3mg 60 tablets: TT50-5241c
- RISPERDAL® risperidone 4mg 60 tablets: TT50-5241d

Janssen has made the decision to discontinue RISPERDAL® tablets for commercial reasons. The decision to discontinue this product is not due to safety or efficacy reasons.

If you are currently treating or planning to treat a patient with RISPERDAL®, there is a reimbursed generic option available in New Zealand.

The therapeutic indications for RISPERDAL® as per the New Zealand Data Sheet are:

- RISPERDAL® is indicated for the treatment of schizophrenia and other psychotic disorders. These include first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted effect, emotional and social withdrawal, poverty of speech) are prominent.
- RISPERDAL® is also indicated for the treatment and long term control of mania in bipolar disorder. These episodes are characterised by symptoms such as elevated, expansive or irritable mood, inflated self esteem, decreased need for sleep, pressured speech, racing thoughts, distractability, or poor judgement, including disruptive or aggressive behaviours.
- RISPERDAL® also alleviates affective symptoms (such as depression, guilt-feelings, anxiety) associated with schizophrenia. In addition, RISPERDAL® also appears effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial response to treatment with this agent.
- RISPERDAL® is indicated for the treatment (up to 12 weeks) of agitation, aggression or psychotic symptoms in patients with moderate to severe dementia of the Alzheimer type.
- RISPERDAL® is also indicated for the treatment of conduct and other disruptive behaviour disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation, or average IQ, in whom destructive behaviours (e.g. aggression, impulsivity and self-injurious behaviours) are prominent. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in children and adolescents who have shown an initial treatment response. Pharmacological treatment should be

an integral part of a more comprehensive treatment program, including psychosocial and educational intervention. Treatment with RISPERDAL® for patients with disruptive behaviour disorders should be initiated only in consultation with a specialist, including child and adolescent psychiatrists, paediatric neurologists, developmental paediatricians, or other physicians conversant in the diagnosis and treatment of conduct and other disruptive behaviour disorders.

- RISPERDAL® is indicated for the treatment of autism in children and adolescents.

Please refer to the full RISPERDAL® Data Sheet should you need any information on this product, available at:
https://innovativemedicine.jnj.com/newzealand/download/risperdal-data-sheet.pdf

Adverse Event and Product Quality Complaints Reporting
Janssen is committed to monitoring the safety of our products. We encourage Healthcare Professionals to report any suspected adverse events and other safety information for RISPERDAL® to Medsafe at https://pophealth.my.site.com/carmreportnz/s/ and/or Janssen's Medical Information Department, and to report product quality complaints to Janssen's Medical Information Department.

If you have further questions, please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com.

Yours sincerely,

Anna Dekkers
Electronically signed by: Anna Dekkers
Reason: I attest to the accuracy and integrity of this document
Date: Sep 24, 2025 12:06:36 GMT+10

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Risperdal® (risperidone) Minimum Data Sheet

RISPERDAL® is a partially funded medicine – a prescription charge will apply.

Description: RISPERDAL® tablets, oral solution

Indications: Schizophrenia and other psychotic disorders; treatment and long term control of mania in bipolar disorder; alleviates affective symptoms associated with schizophrenia; treatment (up to 12 weeks) of agitation, aggression or psychotic symptoms in patients with moderate or severe dementia of the Alzheimer type; conduct and other disruptive behaviour disorders; autism (children and adolescents). See full Data Sheet for details.

Dosage: Schizophrenia - initially 2 mg on day 1; 4 mg day 2; titrate as necessary (usual range 4–6 mg daily given once daily or in 2 divided doses). Bipolar mania – initially 2 mg once daily; increase by 1 mg daily as necessary (usual range 2–6mg daily). Behavioural Disturbances in Dementia – initially 0.25 mg twice daily; increase in increments of 0.25 mg twice daily not more frequently than every other day as necessary (usual range 0.5–1 mg twice daily); once target dose reached, may be given as once daily dose. Conduct disorder – patients >50kg: initially 0.5 mg once daily; increase by 0.5 mg once daily not more frequently than every other day as necessary. The optimum dose is 1 mg once daily (usual range 0.5 - 1.5 mg once daily); patients <50kg: initially 0.25 mg once daily; increase by 0.25 mg once daily not more frequently than every other day as necessary. The optimum dose is 0.5 mg once daily (usual range 0.25 - 0.75 mg once daily). Autism - give once or twice daily based on body weight; initially 0.25 mg or 0.5 mg/day; increased up to 0.5 mg or 1.0 mg/day on day 4; reassess on day 14; rounded doses by weight. Use only the pipette provided with the oral solution for measuring the prescribed dose. See full Data Sheet for details.

Contraindications: Patients with known hypersensitivity to risperidone or excipients.

Precautions: Elderly patients with dementia, particularly with concomitant furosemide; alpha-blocking activity; tardive dyskinesia/extrapyramidal symptoms, especially with concomitant psychostimulants; akathisia; neuroleptic malignant syndrome; Lewy body dementia; Parkinson's disease; hyperglycaemia and diabetes mellitus; leukopenia, neutropenia and agranulocytosis; venous thromboembolism; priapism; body temperature regulation; antiemetic effect; epilepsy or a history of seizures; intraoperative floppy iris syndrome; dysphagia; cardiovascular disease; weight gain; QT interval, especially with history of arrhythmias; risk of suicide; hepatic/renal impairment; pregnancy; lactation; children <15 years in schizophrenia.

Interactions: Centrally acting drugs and alcohol; levodopa and other dopamine agonists; psychostimulants; drug with hypotensive effects; medicines that prolong QT internal or cause electrolyte imbalance; strong CYP2D6 inhibitors (e.g. SSRIs, tricyclic antidepressants, phenothiazines antipsychotics; protease inhibitor antivirals); CYP3A4 (e.g. erythromycin, protease inhibitor antivirals, H2 antagonists) and/or P-gp Inhibitors (e.g. itraconazole, ketoconazole) CYP3A4 and/or P-gp Inducers (e.g. rifampicin, carbamazepine); some beta-blockers; calcium-channel blockers (e.g. verapamil); furosemide (elderly); quinidine.

Adverse Reactions: *Common*: Nasopharyngitis, upper respiratory tract infection, urinary tract infection, influenza, rhinitis, pneumonia, sinusitis, cellulitis; anaemia; hypersensitivity, anorexia; insomnia, agitation, anxiety, nervousness, confusional state, listless; parkinsonism, akathisia, somnolence, dizziness, headache, sedation, tremor, dystonia, lethargy, syncope, reduced consciousness, drooling, dysarthria, disturbance in attention, balance disorder, hypersomnia; vision blurred, conjunctivitis; tardive dyskinesia, cerebrovascular accident, transient ischaemic attack, neuroleptic malignant syndrome, tachycardia, heart rate increased, palpitations, hypotension, orthostatic hypotension, hypertension; epistaxis, rhinorrhea, dyspnoea; musculoskeletal pain, back pain/pain in extremity, arthralgia, posture abnormal, joint swelling, myalgia, enuresis, neck pain; fatigue, asthenia pyrexia, feeling abnormal, sluggishness, chest pain/discomfort; ear pain; pharyngolaryngeal pain, sinus/nasal/pulmonary congestion, cough; nausea, constipation, dyspepsia, vomiting, diarrhoea, salivary hypersecretion, dry mouth, stomach/abdominal pain/discomfort, dysphagia, faecaloma; increased/decreased appetite; rash, dry skin, dandruff, seborrheic dermatitis, hyperkeratosis, pruritus, acne, erythema, pitting oedema/peripheral, gait disturbance/abnormal; urinary incontinence, pollakiuria; ejaculation failure, galactorrhea; blood phosphokinase increased; body temperature increased; weight increased, fall. Others see full Data Sheet.

Presentation: Prescription medicine. Risperdal® film-coated tablets: each film-coated tablet contains 0.5 mg, 1 mg, 2 mg, 3 mg or 4 mg risperidone. Risperdal® oral solution1 mg/mL: 1 mL oral solution contains 1 mg risperidone.

Before prescribing please review full Data Sheet available from https://innovativemedicine.jnj.com/newzealand/download/risperdal-data-sheet.pdf www.medsafe.govt.nz. or

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