Risperdal® Consta® Injection PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Risperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Maintenance treatment of schizophrenia in patients currently stabilised with oral antipsychotics.

DOSAGE & ADMINISTRATION: Intramuscular injection into deltoid muscle (using 21G UTW 1-inch [0.8 mm x 25 mm] safety needle) or gluteal muscle (using 20G TW 2-inch [0.9 mm x 51 mm] safety needle). Adults: 25 mg every two weeks (alternate buttocks/alternate arms); consider 37.5 mg if stabilised on higher doses of the oral antipsychotic used (e.g., > 4 mg/day oral risperidone). Consider 12.5 mg increase after four week interval. Maximum: 50 mg every two weeks. Ensure prior tolerability with oral risperidone. Supplement with oral risperidone or previous antipsychotic for first three weeks. Children: Not recommended. Elderly: No dose adjustment but caution as data limited. Renal and Hepatic impairment: Caution. 25 mg every two weeks if minimum 2 mg oral tolerated following titration.

CONTRAINDICATIONS: Hypersensitivity to active substance or any excipients.

SPECIAL WARNINGS & PRECAUTIONS: Not licensed for treatment of dementia-related behavioural disturbances due to three-fold increased risk of cerebrovascular adverse events. If history of CVA/TIA, consider risk carefully. Care with other risk factors for cerebrovascular disease. Caution in patients with risk factors for VTE; orthostatic hypotension; cardiovascular disease and drugs prolonging QT interval. Increase in mortality rate in elderly with dementia. If tardive dyskinesia, consider stopping all antipsychotic drugs. Parkinson’s disease/dementia with Lewy Bodies. Caution if history of/potential for seizures. If Neuroleptic Malignant Syndrome, stop all antipsychotics. Monitoring in diabetics and those with risk factors for diabetes advisable. Advise of potential for weight gain and monitor regularly. Caution in patients with pre-existing hyperprolactinaemia/possible prolactin-dependent tumours. Evaluate prolactin plasma levels if signs of possible prolactin-related side effects. Advise not to drive or operate machinery if alertness affected. Care when using Risperdal and furosemide in elderly patients with dementia. Leucopenia, neutropenia and agranulocytosis reported monitor and consider discontinuation of Risperdal Consta. Potential disruption of body temperature regulation. Avoid inadvertent injection into a blood vessel. Antiemetic effects observed which may mask symptoms of overdosage or conditions such as intestinal obstruction, Reye’s syndrome and brain tumour. Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, including Risperdal Consta.

SIDE EFFECTS: Very common side effects: Parkinsonism, headache, insomnia, anxiety, depression and upper respiratory tract infection. Common side effects: pneumonia, bronchitis, sinusitis, urinary tract infection, influenza, anaemia, hyperprolactinaemia, hyperglycaemia, weight increased, increased appetite, weight decreased, decreased appetite, sleep disorder, agitation, libido decreased, sedation/somnolence, akathisia, dystonia, dizziness, dyskinesia, tremor, vision blurred, tachycardia, hypertension, hypotension, dyspnoea, pharyngolaryngeal pain, cough, nasal congestion, abdominal pain and discomfort, vomiting, nausea, constipation, gastroenteritis, diarrhoea, dyspepsia, dry mouth, toothache, rash, muscle spasms, musculoskeletal pain, back pain, arthralgia, urinary incontinence, erectile dysfunction, amenorrhoea, galactorrhoea, oedema, pyrexia, chest pain, asthenia, fatigue, pain,
injection site reaction, transaminases increased, gamma-glutamyltransferase increased, fall.

Other side effects include: thrombocytopenia, agranulocytosis, neutropenia, depressed/loss of consciousness, convulsion, cerebrovascular disorder/cerebral ischaemia, tardive dyskinesia, neuroleptic malignant syndrome, diabetic coma, atrial fibrillation, atrioventricular block, electrocardiogram QT prolonged, electrocardiogram abnormal, glaucoma, retinal artery occlusion, intestinal obstruction, ileus, faecaloma, pancreatitis, angioedema, rhabdomyolysis, diabetic ketoacidosis, diabetes mellitus, face oedema, hypothermia, anaphylactic reaction, mania, inappropriate antidiuretic hormone secretion, water intoxication, pulmonary embolism, venous thrombosis, pneumonia aspiration, pulmonary congestion, sleep apnoea syndrome, urinary retention, drug withdrawal syndrome (including in neonates), jaundice, priapism.

Class effects: As with other antipsychotics, very rare cases of QT prolongation (postmarketing with risperidone). Other cardiac effects reported with antipsychotics which prolong QT interval: ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia, sudden death, cardiac arrest and Torsade de Pointes. Postural orthostatic tachycardia syndrome and venous thromboembolism.

Refer to SmPC for other side effects.

PREGNANCY: Should only be used if clearly necessary. Monitor newborns if treatment continues in third trimester of pregnancy.

LACTATION: Use should be weighed against potential risks for the child.

INTERACTIONS: Caution with medicinal products known to prolong QT interval: antiarrhythmics; tricyclic antidepressants; tetracyclic antidepressants; certain antihistamines and antimalarials; other antipsychotics; medicines causing electrolyte imbalance, bradycardia or those which inhibit hepatic metabolism of risperidone. Caution with centrally acting drugs (including alcohol). May antagonise dopamine agonists, adjust dose accordingly. Hypotension observed when using antihypertensives. Concomitant use of CYP3A4 and/or P-gp inducers (e.g. carbamazepine, rifampicin, phenytoin and phenobarbital) may decrease risperidone plasma levels, adjust dose accordingly. CYP2D6 inhibitors (e.g. fluoxetine, paroxetine, quinidine, verapamil), CYP3A4 and/or P-gp inhibitors (e.g. itraconazole, ketoconazole), ritonavir may increase risperidone plasma levels; adjust dose accordingly. Doses of sertraline and fluvoxamine above 100 mg/day may increase plasma concentrations of active antipsychotic fraction. Phenothiazines, tricyclic antidepressants, and some beta-blockers may increase plasma concentrations of risperidone but not those of active antipsychotic fraction.

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: POM.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS & BASIC NHS COSTS

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