

Risperidone

Risdin®

2 mg Tablet • 4 mg Tablet
ANTIPSYCHOTICS



FORMULATION:

Each tablet contains:
Risperidone, USP 2 mg
Risperidone, USP 4 mg

PRODUCT DESCRIPTION:

Risperidone (Risdin) 2 mg is a white, oval-shaped biconvex tablet, plain on one side and scored on the other side.
Risperidone (Risdin) 4 mg is a mottled, green, oval-shaped tablet, plain on one side and scored on the other side.

INDICATION:

Risperidone is used for the treatment of schizophrenia and other psychoses.

CLINICAL PHARMACOLOGY:

PHARMACODYNAMICS:

Risperidone is an atypical antipsychotic drug with high affinity for 5-hydroxytryptamine (5-HT) and dopamine D2 receptors.

PHARMACOKINETICS:

Risperidone is readily absorbed after oral doses, peak plasma concentrations being reached within 1 to 2 hours. It is extensively metabolized in the liver by hydroxylation to its main active metabolite, 9-hydroxyrisperidone; oxidative N-dealkylation is a minor metabolic pathway. Hydroxylation is mediated by the cytochrome P450 isoenzyme CYP2D6 and is the subject of genetic polymorphism. Excretion is mainly in the urine and to a lesser extent, in the feces. Risperidone and 9-hydroxyrisperidone are about 88% and 77% bound to plasma proteins, respectively.

DOSAGE AND ADMINISTRATION:

Initial dose of 2 mg and increased to 4 mg daily in 1 or 2 divided doses but should not exceed 16 mg. For elderly and patients with renal or hepatic impairment: Initial dose of 0.5 mg two times a day and, if necessary, increased to 1 mg to 2 mg two times a day. Or as prescribed by a physician.

W A R N I N G
INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

PRECAUTIONS:

For patients with known cardiovascular (CV) disease, dosage should be gradually titrated as recommended. A dose reduction should be considered if the following occurs: hypotension, renal or liver insufficiency, elderly with dementia, parkinsonism, epilepsy. Monitor for signs of tardive dyskinesia. Caution is advised when operating/driving machinery, for pregnancy & lactation and neuroleptic malignant syndrome.

CONTRAINDICATION:

It may cause hypersensitivity reactions, including anaphylactic reactions and angioedema.

ADVERSE EFFECTS:

Infections and infestations: pneumonia, bronchitis, respiratory tract infection, sinusitis, urinary tract infection, ear infection, influenza, cystitis, eye infection, tonsillitis, onychomycosis, cellulitis localized infection, viral infection, acrodermatitis.

Blood and lymphatic system disorders: neutropenia, decreased in white blood cell count, thrombocytopenia, anemia, decreased in hematocrit, increased in eosinophil count, agranulocytosis.

Immune system disorders: hypersensitivity, anaphylactic reaction.

Endocrine disorders: hyperprolactinemia, inappropriate antidiuretic hormone secretion, presence of glucose in the urine.
Metabolism and nutrition disorders: weight increased, increased or decreased appetite, diabetes mellitus, hyperglycemia, polydipsia, weight decreased, anorexia, blood cholesterol increased, water intoxication, hypoglycemia, hyperinsulinemia, increased blood triglycerides, diabetic ketoacidosis.

Psychiatric disorders: insomnia, sleep disorder, agitation, depression, anxiety, mania, confusional state, decreased libido, nervousness, nightmare, catatonia, somnambulism, sleep-related eating disorder, blunted affect, anorgasmia.

Nervous system disorders: sedation/somnolence, parkinsonism, headache, akathisia, dystonia, dizziness, dyskinesia, tremor, tardive dyskinesia, cerebral ischemia, unresponsive to stimuli, loss of consciousness, depressed level of consciousness, convulsion, syncope, psychomotor hyperactivity, balance disorder, coordination abnormal, dizziness postural, disturbance in attention, dysarthria, dysgeusia, hypoesthesia, paresthesia, neuroleptic malignant syndrome, cerebrovascular disorder, diabetic coma, head titubation.

Eye disorders: vision blurred, conjunctivitis, photophobia, dry eye, increased lacrimation, ocular hyperaemia, glaucoma, eye movement disorder, eye rolling, eyelid margin crusting, floppy iris syndrome (intraoperative).

Ear and labyrinth disorders: vertigo, tinnitus, ear pain.

Cardiac disorders: tachycardia, atrial fibrillation, atrioventricular block, conduction disorder, prolonged electrocardiogram QT, bradycardia, abnormal electrocardiogram, palpitations, sinus arrhythmia.

Vascular disorders: hypertension, hypotension, orthostatic hypotension, flushing, pulmonary embolism, venous thrombosis.

Respiratory, thoracic and mediastinal disorders: dyspnea, pharyngolaryngeal pain, cough, epistaxis, nasal congestion, pneumonia aspiration, pulmonary congestion, respiratory tract congestion, rales, wheezing, dyspnoea, respiratory disorder, sleep apnea syndrome, hyperventilation.

Gastrointestinal disorders: abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhea, dyspepsia, dry mouth, toothache, fecal incontinence, fecaloma, gastroenteritis, dysphagia, flatulence, pancreatitis, intestinal obstruction, swollen tongue, cheilitis, ileus.

Skin and subcutaneous tissue disorders: rash, erythema, urticaria, pruritus, alopecia, hyperkeratosis, eczema, dry skin, skin discoloration, acne, seborrheic dermatitis, skin disorder, skin lesion, drug eruption, dandruff, angioedema.
Musculoskeletal and connective tissue disorders: muscle spasms, musculoskeletal pain, back pain, arthralgia, increased blood creatine phosphokinase, abnormal posture, joint stiffness, joint swelling, muscular weakness, neck pain, rhabdomyolysis.

Renal and urinary disorders: urinary incontinence, pollakiuria, urinary retention, dysuria.

Pregnancy, puerperium, and neonatal conditions: drug withdrawal syndrome neonatal.

Reproductive system and breast disorders: erectile dysfunction, ejaculation disorder, amenorrhea, menstrual disorder, gynecomasia, galactorrhea, sexual dysfunction, breast pain, breast discomfort, vaginal discharge, priapism, delayed menstruation, breast engorgement, breast enlargement, breast discharge.

General disorders and administration site conditions: edema, pyrexia, chest pain, asthenia, fatigue, pain, face edema, chills, increased or decreased body temperature, gait abnormal, thirst, chest discomfort, malaise, feeling abnormal, discomfort, hypothermia, peripheral coldness, drug withdrawal syndrome, induration.

Hepatobiliary disorders: increased transaminases, increased gamma-glutamyl transferase, increased hepatic enzyme jaundice.

Injury, poisoning and procedural complications: fall, procedural pain.

*"For suspected adverse drug reaction, report to FDA: www.fda.gov/ph.
Seek medical attention immediately at the first sign of any adverse drug reaction."*

DRUG INTERACTIONS:

Hypotensive drugs: Risperidone (Risdin) tablet may potentiate the hypotensive effects of these drugs.
Levodopa and Dopamine Agonists: Risperidone (Risdin) tablet may antagonize the effects of these agents.
H2-Receptor Antagonists (Cimetidine and Ranitidine): These drugs increase the bioavailability of Risperidone.
Clonidine: May decrease the clearance of Risperidone.
Valproate: Risperidone may increase peak plasma concentration of this drug.
Drugs that Inhibit CYP2D6 and Other CYP Isozymes: Drug interactions that reduce the metabolism of Risperidone to its active metabolite, 9-hydroxyrisperidone, would increase the plasma concentrations of Risperidone and lower the concentrations of 9-hydroxyrisperidone.
Selective Serotonin Reuptake Inhibitors (Fluoxetine and Paroxetine): Increase plasma concentrations of Risperidone.

PREGNANCY AND LACTATION:

Pregnancy Category C - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.
Nursing mothers receiving Risperidone (Risdin) tablet should discontinue breastfeeding because Risperidone is excreted in breast milk.

OVERDOSE AND MANAGEMENT:

Signs and symptoms of Risperidone (Risdin) tablet overdose are generally its pharmacological effects which include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. Other symptoms may include hyponatremia, hypokalemia, QT prolongation, QRS widening, seizure, and convulsion. Torsade de pointes may occur when this drug is combined with Paroxetine.

In case of acute overdose, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered.

The possibility of obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias. Administration of antiarrhythmic agents (Disopyramide, Procainamide, and Quinidine) have a theoretical hazard of QT-prolonging effects that might be additive to those of Risperidone. Similarly, it is reasonable to expect that the alpha-blocking properties of Brevitium might be additive to those of Risperidone, resulting in problematic hypotension.

General supportive measures should immediately be instituted during overdose of Risperidone (Risdin) tablet. The possibility of multiple drug involvement should be considered. Hypotension and circulatory collapse should be treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents (epinephrine and dopamine should not be used, since beta stimulation may worsen hypotension in the setting of risperidone-induced alpha blockade). In cases of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.
Keep out of reach of children.

AVAILABILITY:

Risperidone (Risdin) 2 mg tabletAlu-PVC White opaque Blister x 10's (Box x 100's)
Registration No.: DR-XY37076
Date of First Authorization: November 2009

Risperidone (Risdin) 4 mg tabletAlu-PVC White opaque Blister x 10's (Box x 100's)
Registration No.: DR-XY37075
Date of First Authorization: November 2009

Date of Revision of Package Insert: September 2019

Manufactured for:
MEDCHOICE CNS PHARMA CORPORATION
Unit 1001, 88 Corporate Center, Valero corner Sedeño Streets,
Salcedo Village, Makati, Metro Manila

By:
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