# Orsidon

**Tablets**

(Risperidone) USP

**Composition:**
**Orsidon 1mg Tablet:** Each film coated tablet contains:
Risperidone (USP).....1mg
**Orsidon 2mg Tablet:** Each film coated tablet contains:
Risperidone (USP).....2mg
**Orsidon 3mg Tablet:** Each film coated tablet contains:
Risperidone (USP).....3mg
**Orsidon 4mg Tablet:** Each film coated tablet contains:
Risperidone (USP).....4mg

**Description:**
Orsidon contains Risperidone, a psychotropic agent belonging to the chemical class of Benzisoxazole derivatives.

**Mechanism of Action:**
The mechanism of action as with other drugs used to treat schizophrenia is unknown. However, it has been proposed that the drug's therapeutic activity in schizophrenia is mediated through a combination of dopamine type 2 ($D_2$) and serotonin type 2 ($5HT_2$) receptor antagonism.

**Pharmacodynamics:**
Risperidone is a selective monoaminergic antagonist with unique properties. The clinical effect from Orsidon results from the combined concentrations of Risperidone and its major metabolite, 9-hydroxyrisperidone.

**Pharmacokinetics:**
**Absorption and Distribution:**
Orsidon is well absorbed. The absolute oral bioavailability of Risperidone is 70%. The relative oral bioavailability of Risperidone from a tablet is 94%. When compared to solution, mean peak plasma concentrations of Risperidone occurred at about 1 Hour.
**Metabolism and Excretion:**
Risperidone is extensively metabolized in the liver. The main metabolic pathway is through hydroxylation of Risperidone to 9-hydroxyrisperidone by the enzyme, CYP2D6. A minor metabolic pathway is through N-dealkylation. The main metabolite, 9-hydroxyrisperidone, has similar pharmacological activity as Risperidone.
**Renal Impairment:**
In patients with moderate to severe renal disease, clearance of the sum of Risperidone and its active metabolite decreased by 60% compared to young healthy subjects.
**Elderly:**
In healthy elderly subjects, renal clearance of both Risperidone and 9-hydroxyrisperidone may decrease and elimination half-lives may prolong compared to young healthy subjects.

**Pediatrics:**
The pharmacokinetics of Risperidone and 9-hydroxyrisperidone in children is similar to those in adults.
**Indications:**
Orsidon is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychosis, Orsidon is also indicated for treatments of:
- Behavioral Disturbance
- Adjunctive therapy to mood stabilization
- Bipolar Mania
- Irritability Associated with Autistic Disorder

**Contraindications:**
Orsidon is contraindicated in patients with a known hypersensitivity to the product. As a result, anaphylactic reaction may occur.

**Warnings:**
Increased mortality in elderly patients with dementia-related problems. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Orsidon (Risperidone) is not approved for the treatment of dementia-related psychosis.

**Neuroleptic Malignant Syndrome (NMS):**
A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status.
**Hyperglycemia and Diabetes Mellitus:**
Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics, including Orsidon, should be monitored regularly for worsening of glucose control.
**Orthostatic Hypotension:**
Orsidon may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose period, probably reflecting its alpha-adrenergic antagonistic properties.

**PRECAUTIONS:**
**Body Temperature Regulation:**
Disruption of body temperature regulation has been attributed to antipsychotic agents. Both hypothermia and hyperthermia have been reported in association with oral Orsidon use. Caution is advised when prescribing for patients who will be exposed to temperature extremes.
**Pregnancy Category C:**
Neonates exposed to antipsychotic drugs (including Orsidon) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. So it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
**Labor and Delivery:**
The effect of Orsidon on labor and delivery in humans is unknown.
**Nursing Mothers:**
Risperidone and 9-hydroxyrisperidone are excreted in milk. Risperidone and 9-hydroxyrisperidone are also excreted in human breast milk. Therefore, women receiving Orsidon should not

breastfeed.

**DRUG INTERACTIONS:**

**Centrally-Acting Drugs and Alcohol:**

Given the primary CNS effects of Risperidone, caution should be used when Orsidon is taken in combination with other centrally-acting drugs and alcohol.

**Drugs with Hypotensive Effects:**

Because of its potential for inducing hypotension, Orsidon may enhance the hypotensive effects of other therapeutic agents with this potential.

**Levodopa and Dopamine Agonists:**

Orsidon may antagonize the effects of levodopa and dopamine agonists.

**Amitriptyline:**

Amitriptyline does not affect the pharmacokinetics of Risperidone and 9-hydroxyrisperidone.

**Lithium:**

Repeated oral doses of Orsidon (3 mg twice daily) did not affect the exposure (AUC) or peak plasma concentrations (Cmax) of lithium.

**Clozapine:**

Chronic administration of clozapine with Orsidon may decrease the clearance of Risperidone.

**ADVERSE REACTIONS:**

Following adverse effects may be observed.

**Nervous System Disorders:**

Balance disorder, disturbance in attention, unresponsive to stimuli, depressed level of consciousness, movement disorder, speech disorder, loss of consciousness.

**Musculoskeletal and Connective Tissue Disorders:**

Joint swelling musculoskeletal chest pain, posture abnormal, neck pain, muscular weakness.

**Gastrointestinal Disorders:**

Nausea, constipation, dry mouth, abdominal discomfort, dyspepsia.

**General Disorders:**

Edema peripheral, thirst, gait disturbance, influenza-like illness, edema, chills, chest discomfort, face edema, discomfort, generalized edema, drug withdrawal syndrome, peripheral coldness.

**Immune System Disorders:**

Drug hypersensitivity.

**Cardiac Disorders:**

Sinus bradycardia, sinus tachycardia.

**OVERDOSE:**

The most frequently reported signs and symptoms are those resulting from an exaggeration of the drug's known pharmacological effects, i.e. drowsiness, sedation, tachycardia, hypotension, and extrapyramidal symptoms. Other adverse reactions may also be reported. Postmarketing experience includes reports of acute Orsidon overdosage, with estimated doses of up to 360 mg.

**Management of Overdosage:**

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

**Tardive Dyskinesia:**

A syndrome of potentially irreversible, involuntary dyskinetic movements may develop in patients treated with antipsychotic drugs. If symptoms of tardive dyskinesia appear in a patient treated with the drug, discontinuation should be considered.

**Dosage and Administration:**

Orsidon should be administered once or twice daily. Initial dosing is generally 2 mg/day. Dose increases should then occur at intervals not less than 24 hours, in increments of 1-2 mg/day, as tolerated, to a recommended dose of 4-8mg/day.

**Adolescents:**

The dosage of Orsidon should be initiated at 0.5mg once daily, administered as a single daily dose in either the morning or evening.

**Bipolar Mania:** Usual Dose:

Orsidon should be administered on a once-daily schedule, starting with 2mg to 3mg per day.

**Dosage in Special Populations:**

The recommended initial dose is 0.5mg twice daily in patients who are elderly or debilitated, patients with severe renal or hepatic impairment, and patients either predisposed to hypotension or for whom hypotension would pose risk.

**Usual Pediatric Dose for Bipolar Disorder**

Initial dose: 0.5mg once a day.

**Usual Pediatric Dose for Autism:**

Initial dose: 0.25mg orally once a day

**Storage:**

Store at 15-30°C. Protect from heat, light, and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

**How Supplied:**

**Orsidon 1mg Tablets:** are available in Alu-Alu pack of 1 x 10's.
**Orsidon 2mg Tablets:** are available in Alu-Alu pack of 1 x 10's.
**Orsidon 3mg Tablets:** are available in Alu-Alu pack of 1 x 10's.
**Orsidon 4mg Tablets:** are available in Alu-Alu pack of 1 x 10's.

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# اورسیڈون

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(رسپیریڈون) یو ایس پی

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**خوراک:** دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

**ہدایات:** دوا کو 15-30° سینٹی گریڈ پر رکھیں۔
گرمی، روشنی اور نمی سے محفوظ رکھیں۔ تمام دوائیں بچوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

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Manufactured by:
**STANDPHARM PAKISTAN (PVT) LTD**
20 Km Ferozepur Road Lahore, Pakistan.
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