

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use risperidone safely and effectively. See full prescribing information for risperidone.

risperidone Orally Disintegrating Tablets, USP
Initial U.S. Approval: 1993

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
See full prescribing information for complete boxed warning.
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Risperidone is not approved for use in patients with dementia-related psychosis. (5.1)

INDICATIONS AND USAGE

- Risperidone is an atypical antipsychotic indicated for:
- Treatment of schizophrenia (1.1)
 - As monotherapy or adjunctive therapy with lithium or valproate, for the treatment of acute manic or mixed episodes associated with Bipolar 1 Disorder (1.2)
 - Treatment of irritability associated with autistic disorder (1.3)

DOSAGE AND ADMINISTRATION

Recommended Daily Dosage:

	Initial Dose	Target Dose	Effective Dose Range
Schizophrenia - adults (2.1)	2 mg	4 to 8 mg	4 to 16 mg
Schizophrenia - adolescents (2.1)	0.5 mg	3 mg	1 to 6 mg
Bipolar mania - adults (2.2)	2 to 3 mg	1 to 6 mg	1 to 6 mg
Bipolar mania - children and adolescents (2.2)	0.5 mg	1 to 2.5 mg	1 to 6 mg
Irritability associated with autistic disorder (2.3)	0.25 mg (Weight <20 kg) or 0.5 mg (Weight ≥ 20 kg)	0.5 mg (<20 kg) or 1 mg (≥ 20 kg)	0.5 to 3 mg

- Severe Renal or Hepatic Impairment in Adults: Use a lower starting dose of 0.5 mg twice daily. May increase to dosages above 1.5 mg twice daily at intervals of at least one week. (2.4)
- Orally Disintegrating Tablets: Open the blister only when ready to administer, and immediately place tablet under tongue. Can be swallowed with or without liquid. (2.7)

DOSAGE FORMS AND STRENGTHS

- Orally disintegrating tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to risperidone (4)
- WARNINGS AND PRECAUTIONS**

- Cerebrovascular events, including stroke, in elderly patients with dementia-related psychosis: Risperidone is not approved for use in patients with dementia-related psychosis (5.2)
- Neuroleptic Malignant Syndrome: Manage with immediate discontinuation of Risperidone and close monitoring (5.3)
- Tardive dyskinesia: Consider discontinuing Risperidone if clinically indicated. (5.4)
- Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. (5.5)
 - **Hyperglycemia and Diabetes Mellitus:** Monitor patients for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Monitor glucose regularly in patients with diabetes or at risk for diabetes. (5.5)
 - **Dyslipidemia:** Undesirable alterations have been observed in patients treated with atypical antipsychotics. (5.5)
- **Weight Gain:** Significant weight gain has been reported. Monitor weight gain. (5.5)
- **Hyperprolactinemia:** Prolactin elevations occur and persist during chronic administration. (5.6)
- Orthostatic hypotension: For patients at risk, consider a lower starting dose and slower titration. (5.7)
- Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of clinically significant low white blood cell count (WBC). Consider discontinuing Risperidone if a clinically significant decline in WBC occurs in the absence of other causative factors. (5.8)
- Potential for cognitive and motor impairment: Use caution when operating machinery. (5.9)
- Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. (5.10)

ADVERSE REACTIONS

The most common adverse reactions in clinical trials (≥5% and twice placebo) were parkinsonism, akathisia, dystonia, tremor, sedation, dizziness, anxiety, blurred vision, nausea, vomiting, upper abdominal pain, stomach discomfort, dyspepsia, diarrhea, salivary hypersecretion, constipation, dry mouth, increased appetite, increased weight, fatigue, nasal congestion, upper respiratory tract infection, nasopharyngitis and pharyngolaryngeal pain. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Par Pharmaceutical, Inc. at 1-800-828-9393 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Carbamazepine and other enzyme inducers decrease plasma concentrations of risperidone. Increase the risperidone dose up to double the patient's usual dose. Titrate slowly. (7.1)
- Fluoxetine, paroxetine, and other CYP 2D6 enzyme inhibitors increase plasma concentrations of risperidone. Reduce the initial dose. Do not exceed a final dose of 8mg per day of risperidone. (7.1)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm. (8.1)
- Nursing Mothers: Discontinue drug or nursing, taking into consideration the importance of drug to the mother. (8.3)

See 17 FOR PATIENT COUNSELING INFORMATION.

Revised: 06/2015

FULL PRESCRIBING INFORMATION: CONTENTS*
WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

1 INDICATIONS AND USAGE

- Schizophrenia
- Bipolar Mania
- Irritability Associated with Autistic Disorder

2 DOSAGE AND ADMINISTRATION

- Schizophrenia
- Bipolar Mania
- Irritability Associated with Autistic Disorder-Pediatrics (Children and Adolescents)
- Dosing in Patients with Severe Renal or Hepatic Impairment
- Dose Adjustments for Specific Drug Interactions
- Directions for Use of Risperidone Orally Disintegrating Tablets, USP

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- Increased Mortality in Elderly Patients with Dementia-Related Psychosis
- Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis
- Neuroleptic Malignant Syndrome
- Tardive Dyskinesia
- Metabolic Changes
- Hyperprolactinemia
- Orthostatic Hypotension
- Leukopenia, Neutropenia, and Agranulocytosis
- Potential for Cognitive and Motor Impairment
- Seizures
- Dysphagia
- Priapism
- Body Temperature Regulation
- Patients with Phenyketonuria

6 ADVERSE REACTIONS

- Clinical Trials Experience
- Postmarketing Experience

7 DRUG INTERACTIONS

- Pharmacokinetic-related Interactions
- Pharmacodynamic-related Interactions

8 USE IN SPECIFIC POPULATIONS

- Pregnancy
- Labor and Delivery
- Nursing Mothers
- Pediatric Use
- Geriatric Use
- Renal Impairment
- Hepatic Impairment
- Patients with Parkinson's Disease or Lewy Body Dementia

9 DRUG ABUSE AND DEPENDENCE

- Controlled Substance
- Abuse
- Dependence

10 OVERDOSAGE

- Human Experience
- Management of Overdosage

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- Mechanism of Action
- Pharmacodynamics
- Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

- Carcinogenesis, Mutagenesis, Impairment of Fertility
- Animal Toxicology

14 CLINICAL STUDIES

- Schizophrenia
- Bipolar Mania - Monotherapy
- Bipolar Mania - Adjunctive Therapy with Lithium or Valproate
- Irritability Associated with Autistic Disorder

16 HOW SUPPLIED/STORAGE AND HANDLING

- How Supplied
- Storage and Handling

17 PATIENT COUNSELING INFORMATION

- Orthostatic Hypotension
- Interference with Cognitive and Motor Performance

- Pregnancy
- Nursing
- Concomitant Medication
- Alcohol
- Phenyleketonurics
- Metabolic Changes
- Tardive Dyskinesia

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

Rx Only

WARNING: 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. Risperidone is not approved for the treatment of patients with dementia-related psychosis. (See WARNINGS AND PRECAUTIONS (5.1))

1 INDICATIONS AND USAGE

- Schizophrenia
Risperidone is indicated for the treatment of schizophrenia. Efficacy was established in 4 short-term trials in adults, 3 short-term trials in adolescents (ages 13 to 17 years), and one long-term maintenance trial in adults. (See CLINICAL STUDIES (14.1), (14.2), and (14.3))
- Bipolar Mania
Risperidone is indicated for the treatment of acute manic or mixed episodes associated with Bipolar 1 Disorder. Efficacy was established in 2 short-term trials in adults and one short-term trial in children and adolescents (ages 10 to 17 years). (See CLINICAL STUDIES (14.2))

Adults
Risperidone is indicated for the treatment of acute manic or mixed episodes associated with Bipolar 1 Disorder. Efficacy was established in one short-term trial in adults (See CLINICAL STUDIES (14.3)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Adults
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Children and Adolescents
Risperidone is indicated for the treatment of irritability associated with autistic disorder including symptoms of aggression towards others, self-harm, and frequent tantrums, and rapidly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) (See CLINICAL STUDIES (14.4)).

Do not open the blister until ready to administer. For single tablet removal, separate one of the four or six blister units by tearing apart at the perforation and bend the corner where indicated. Peel back fold to expose the tablet. Do NOT put the tablet through the fold because this could damage the tablet.

Tablet Administration

Using dry hands, remove the tablet from the blister unit and immediately place the entire Risperidone Orally Disintegrating Tablet on the tongue. The Risperidone Orally Disintegrating Tablet should be crumbled immediately, as the tablet cannot be stored once removed from the blister unit. Risperidone Orally Disintegrating Tablets, USP disintegrate in the mouth within seconds and can be swallowed subsequently with or without liquid. Patients should not attempt to split or to chew the tablet.

3 DOSAGE FORMS AND STRENGTHS

Risperidone Orally Disintegrating Tablets, USP are available in the following strengths: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg. All are round shaped, white in color and imprinted with "P" on one side and either "212", "311", "315", "401", "402", or "403" on the other side according to their respective strengths.

4 CONTRAINDICATIONS

Risperidone is contraindicated in patients with a known hypersensitivity to risperidone. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been observed in patients treated with risperidone.

5 WARNINGS AND PRECAUTIONS

5.1 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. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

In two of four placebo-controlled trials in elderly patients with dementia-related psychosis, a higher incidence of mortality was observed in patients treated with risperidone plus risperidone when compared to patients treated with risperidone alone or with placebo plus risperidone. No pathological mechanism has been identified to explain this finding, and no consistent pattern for cause of death was observed.

Risperidone is not approved for the treatment of dementia-related psychosis (see **BOXED WARNING**).

5.2 Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis
Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73 to 97) in trials of risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with risperidone compared to patients treated with placebo. Risperidone is not approved for the treatment of patients with dementia-related psychosis. (See also **BOXED WARNING** and **WARNINGS AND PRECAUTIONS (5.1)**.)

5.3 Neuroleptic Malignant Syndrome
Antipsychotic drugs, including risperidone, can cause a potentially fatal symptom complex referred to as Neuroleptic Malignant Syndrome (NMS). Clinical manifestations of NMS include hyperreflexia, muscle rigidity, altered mental status, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase (CPK), myoglobinuria, rhabdomyolysis, and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis,

