Risperidone is an atypical antipsychotic agent indicated for:

- Usual Dose

Risperidone orally disintegrating tablets can be administered once or twice daily. Initial dosing is generally

- Monotherapy - Adults and Pediatrics

Due to Janssen Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled for use

- HIGHLIGHTS OF PRESCRIBING INFORMATION

To report SUSPECTED ADVERSE REACTIONS, contact Dr. Reddy's Laboratories, Inc. at 1-888-375-3784 or FDA

- ADVERSE REACTIONS

The most common adverse reactions that were associated with discontinuation from clinical trials were somnolence,
Risperidone and its metabolites are eliminated via the urine and, to a much lesser extent, via the feces. As illustrated by a mass balance study of a single 1 mg oral dose of 14C-risperidone administered as solution to three healthy male volunteers, approximately 3% of the radioactivity was recovered in the urine and 0.1% in the feces, with about 95% of the radioactivity excreted as unchanged Risperidone. The major metabolites contained 14C-risperidone and 9-hydroxyrisperidone, with 14C-risperidone being the major metabolite. The respective amounts of radioactivity excreted as 14C-risperidone and 9-hydroxyrisperidone amounted to approximately 17% and 5% of the dose, respectively. In healthy volunteers, following oral administration of a single dose of 14C-risperidone, serum levels of unchanged Risperidone were higher in patients with impaired renal function than in healthy volunteers (75% vs. 25% of the dose administered). In patients with a creatinine clearance rate of less than 30 ml/min, the exposure (AUC) to unchanged Risperidone was 1.9 times greater than that in healthy volunteers. In patients with a creatinine clearance rate of less than 10 ml/min, the exposure (AUC) was 17.4 times greater than that in healthy volunteers.

In patients with liver cirrhosis (Child Class B), the exposure (AUC) to unchanged Risperidone was 1.4 times greater than that in healthy volunteers, whereas the exposure (AUC) was 5.8 times greater in patients with a moderate or severe impairment of liver function (Child Class C) compared to healthy volunteers. In patients with severe liver function impairment (Child Class C) and a creatinine clearance rate of less than 30 ml/min, the exposure (AUC) was 10.1 times greater than that in healthy volunteers.

The steady-state volume of distribution of Risperidone is 0.25 L/kg and is not significantly affected by age or gender, even in patients with severe liver function impairment. In patients with impaired glucose metabolism, the pharmacokinetics of Risperidone were not significantly affected by the presence of diabetes.

Due to Janssen Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled for use in patients less than 18 years of age. Therefore, this drug is not indicated for use in children or adolescents. The safety and effectiveness of Risperidone in children or adolescents have not been established in adequate and well-controlled studies. Use of Risperidone in children or adolescents is currently being evaluated in clinical trials.

In pediatric patients with schizophrenia, bipolar mania or autistic disorder, information regarding changes in ECG intervals is not available. However, a small number of pediatric patients were studied using 24-hour Holter monitoring. In these trials, the incidence of resting ECG abnormalities was similar in risperidone-treated patients and placebo-treated patients. These findings are consistent with findings in adults treated with Risperidone. There was no evidence that the ECG changes were clinically significant.

Risperidone is associated with an increased risk of orthostatic hypotension. In clinical trials, the orthostatic hypotension was observed in 1% of patients treated with placebo, 1% of patients treated with risperidone 0.25 mg twice daily, 2% of patients treated with risperidone 0.5 mg twice daily, 3% of patients treated with risperidone 1 mg twice daily, and 3% of patients treated with risperidone 2 mg twice daily. However, in clinical trials, the incidence of orthostatic hypotension was similar in placebo-treated patients and placebo-treated patients with impaired renal function. A total of 14 patients with a creatinine clearance rate of less than 30 ml/min experienced orthostatic hypotension, whereas 15 patients with a creatinine clearance rate of less than 30 ml/min experienced orthostatic hypotension in placebo-treated patients. In pediatric patients with schizophrenia, bipolar mania or autistic disorder, information regarding changes in ECG intervals is not available.

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