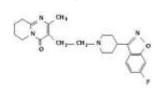
## (100 % EXPORT QUALITY MEDICINE









**RISPERIDONE GENEIC** ® (risperidone) is used for the treatment of schizophrenia in adults and adolescents ages 13-17 years.

RISPERIDONE GENEIC ® (risperidone) is used alone or in combination with other medicines (valproate or lithium) in adults for the short-term treatment of bipolar mania; or alone in adults, children and adolescents ages 10-17 years for the short-term treatment of bipolar mania.

**RISPERIDONE GENEIC** ® (risperidone) is used for the treatment of irritability associated with autistic disorder in children and adolescents ages 5-16 years.

## IMPORTANT SAFETY INFORMATION FOR RISPERIDONE GENEIC ® RISPERIDONE TABLETS

Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. **RISPERIDONE GENEIC** ® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

The most common adverse reactions observed in all clinical trials with **RISPERIDONE GENEIC** ® occurring at a rate of at least 10% were somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, tremors, muscle stiffness, abdominal pain, anxiety, nausea, dizziness, dry mouth, rash, restlessness, and indigestion.

Neuroleptic Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with **RISPERIDONE GENEIC** ® and similar medicines. Call your doctor immediately if the person being treated develops symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment should be stopped if the person being treated has NMS.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with **RISPERIDONE GENEIC** ® and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is no known treatment for TD, but it may go away partially or completely if therapy is stopped.

**RISPERIDONE GENEIC** ® and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection. The connection between prolactin levels and side effects is unknown.

High blood sugar and diabetes have been reported with **RISPERIDONE GENEIC** ® and similar medications. If the person being treated has diabetes or risk factors such as being overweight or a family history of diabetes, blood sugar testing should be performed at the beginning and throughout treatment. Complications of diabetes can be serious and even life threatening. If signs of high blood sugar or diabetes develop, such as being Thirsty all the time, going to the bathroom a lot, or feeling weak or hungry, contact your doctor.

**RISPERIDONE GENEIC** ® should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

Some people taking **RISPERIDONE GENEIC** ® may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side effect may be reduced or it may go away over time.

Extrapyramidal Symptoms (EPS) are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. If you observe any of these symptoms, talk to your healthcare professional.

Some medications interact with **RISPERIDONE GENEIC** ® . Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while taking **RISPERIDONE GENEIC** ® .

Inform your healthcare professional if you are pregnant or if you are planning to get pregnant while taking **RISPERIDONE GENEIC** @.

WARNING: Do not breast-feed if you are taking RISPERIDONE GENEIC.

**RISPERIDONE GENEIC** ® may affect your driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERIDONE GENEIC ® may affect alertness and motor skills; use caution until the effect of RISPERIDONE GENEIC is known.

**Note**: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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