RISPERDAL® CONSTA® (risperidone) is approved for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

Models are used for illustrative purposes only.

FIND OUT more about RISPERDAL® CONSTA®

TALK to your doctor to see if RISPERDAL® CONSTA® is right for you

LEARN more about living with Bipolar I Disorder

Learn About RISPERDAL® CONSTA® (risperidone)

Long-acting medication for people living with Bipolar I Disorder that's taken every 2 weeks—and proven to significantly delay time to relapse.

RISPERDAL® CONSTA® is the only long-acting injectable medication approved for the maintenance treatment of Bipolar I Disorder and can be used as monotherapy—which means that if your doctor decides you only need one medication to control your Bipolar I Disorder, this could be it. RISPERDAL® CONSTA® can also be used in combination with lithium or valproate. If you're concerned about keeping up with your daily medication, ask your doctor if RISPERDAL® CONSTA® is right for you.

In a study of people taking RISPERDAL® CONSTA®, the most common side effects in the treatment of bipolar were weight gain (when used alone) and slow movements, with tremor, stiffness and a shuffling walk (when used with lithium or valproate). This is not a complete list of all possible side effects. Please see **Important Safety Information** for full list. If you have any questions about RISPERDAL® CONSTA® or your therapy, talk with your doctor.

IMPORTANT SAFETY INFORMATION and INDICATION

RISPERDAL CONSTA® (risperidone) is approved for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

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

Do not receive RISPERDAL CONSTA® if you are allergic to paliperidone, risperidone, or any of the ingredients in RISPERDAL CONSTA®.

Neuroleptic, Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with RISPERDAL CONSTA® 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 RISPERDAL CONSTA® 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.

Atypical antipsychotic drugs have been associated with metabolic changes that can increase cardiovascular/cerebrovascular risks. These changes may include:

High blood sugar and diabetes have been reported with RISPERDAL CONSTA® and similar medicines. If you already have diabetes or have risk factors such as being overweight or a family history of diabetes, blood sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening. Call your doctor if you develop signs of high blood sugar or diabetes, such as being thirsty all the time, having to urinate or "pass urine" more often than usual, or feeling weak or hungry.

Changes in cholesterol and triglycerides have been noted in patients taking atypical antipsychotics. Check with your doctor while on treatment.

Weight gain has been reported in patients taking atypical antipsychotics. Monitor weight gain while on treatment.

RISPERDAL CONSTA® 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.

Some people taking RISPERDAL CONSTA® 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 can be reduced or it may go away over time.

Blood problems such as low numbers of white blood cells have been reported in patients taking risperidone and similar medications. In some cases it has been serious and life-threatening. Depending upon your medical condition, your doctor may choose to test your blood as you start therapy with RISPERDAL CONSTA®.

RISPERDAL CONSTA® may affect your alertness or driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERDAL CONSTA® 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.

Painful, long-lasting erections have been reported with the use of RISPERDAL CONSTA®. Call your doctor immediately if you think you are having this problem.

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.

Inform your healthcare professional if you become pregnant or intend to become pregnant during therapy with RISPERDAL CONSTA®. Caution should be used when administering RISPERDAL CONSTA® to a nursing woman.

RISPERDAL CONSTA® may make you more sensitive to heat. You may have trouble cooling off, or be more likely to become dehydrated, so take care when exercising or when doing things that make you warm.

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

In studies of people taking RISPERDAL CONSTA®, the most common side effects in the treatment of schizophrenia were headache, slow movements (including tremor [shaking], stiffness, and a shuffling walk), dizziness, restlessness, tiredness, constipation, indigestion, sleepiness, weight gain, pain in the limbs, and dry mouth.

In studies of people taking RISPERDAL CONSTA®, the most common side effects in the treatment of bipolar disorder were weight gain (when used alone) and slow movements (including with tremor [shaking], stiffness, and a shuffling walk) and tremor (when used with lithium or valproate).

This is not a complete list of all possible side effects. Ask your doctor or treatment team if you have any questions or want more information.

If you have any questions about RISPERDAL CONSTA® or your therapy, talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information including Boxed WARNING for RISPERDAL CONSTA®.

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