TOLAZ LA

For the use of a Neurologist and Psychiatrists Only

Abbreviated Prescribing information for TOLAZ LA [Combipack of Olanzapine Pamoate Prolonged release Powder for suspension for IM Injection-210mg/vial, 300mg/vial, 405mg/vial, Vial of Vehicle, One 3-ml syringe, Three 19-gauge, 1.5-inch (38 mm) Hypodermic Needles with protection device] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Olanzapine is an atypical antipsychotic and its effect is mediated through a combination of dopamine and serotonin type 2 ($5HT_2$) antagonism. **INDICATION:** Olanzapine Pamoate Prolonged Release Powder for Suspension for IM Injection is indicated for the treatment of schizophrenia. **DOSAGE AND ADMINISTRATION**: 150mg/2wks, 300mg/4wks, 210mg/2wks, 405mg/4wks, or 300mg/2wks. See full prescribing information for dosing recommendations. **TOLAZ LA is intended for deep intramuscular gluteal injection only.** Be aware that TOLAZ INJECTION should not be confused with TOLAZ LA. Establish tolerability with oral olanzapine prior to initiating treatment. Olanzapine pamoate doses above 405 mg every 4 weeks or 300 mg every 2 weeks have not been evaluated in clinical trials. Use in specific populations (including renal and hepatic impaired, and pediatric population) has not been studied. Must be suspended using only the diluent for TOLAZ LA provided in the convenience kit. C**ONTRAINDICATION**: Hypersensitivity to the active substance or to any of the excipients. Patients with known risk of narrow-angle glaucoma. **WARNINGS & PRECAUTIONS**: Risk of post-injection delirium/sedation syndrome, increased mortality in elderly patients with dementia-related psychosis, suicide, neuroleptic malignant syndrome (NMS), hyperglycemia, hyperlipidemia, weight gain, tardive dyskinesia, orthostatic/postural hypotension, leukopenia, neutropenia, agranulocytosis, dysphagia, seizures, cognitive and motor impairment, disruption of body temperature regulation, use in patients with concomitant illness and hyperprolactinemia. Patients are recommended to do fasting blood glucose testing and lipid profile at the beginning of, and periodically during, treatment. **DRUG INTERACTIONS**: Interacts with diazepam, CYP1A2 inducers (carbamazepine), alcohol, CYP1A2 inhibitors (fluvoxamine), CYP2D6 inhibitors (fluoxetine), warfarin, CNS acting drugs, antihypertensive agents, levodopa and dopamine agonists and lorazepam (IM). **ADVERSE REACTIONS**: Headache, sedation, weight gain, cough, diarrhea, back pain, nausea, somnolence, dry mouth, nasopharyngitis, increased appetite, vomiting, dystonia, cerebrovascular accident, intestinal obstruction, osteoporosis, libido decreased, lung edema, abnormality of accommodation, amenorrhea, breast pain, menorrhagia, allergic reaction (e.g., anaphylactoid reaction, angioedema, pruritus or urticaria), diabetic coma, diabetic ketoacidosis, discontinuation reaction (diaphoresis, nausea, or vomiting), jaundice, pancreatitis, priapism, rhabdomyolysis, and venous thromboembolic events (including pulmonary embolism and deep venous thrombosis).

MARKETED BY:

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(Additional information is available on request)