

STORAGE GUIDE

How to keep WELTRUZA™ ready to reconstitute[1]

WELTRUZA arrives refrigerated. Store WELTRUZA at room temperature to help keep it ready for use.

*WELTRUZA is the only FDA-approved subcutaneous formulation of olanzapine.[1]

†In an 8-week, randomized, double-blind, placebo-controlled study in adults with acute schizophrenia exacerbation (N=659), the primary endpoint (318 mg, 425 mg, and 531 mg) showed greater reductions in Positive and Negative Syndrome Scale (PANSS) total score (-21.91, -23.44, and -21.93, respectively) versus placebo (-12.17). At week 8, the secondary endpoint was Personal and Social Performance (PSP), where scores improved by 10.31, 8.83, and 10.59, respectively, for WELTRUZA doses versus 5.59 for placebo.[1,3]

People featured are not actual patients, caregivers, or doctors.

Learn more on the back cover

INDICATION AND USAGE

WELTRUZA™ (olanzapine) for extended-release injectable suspension is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

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. WELTRUZA is not approved for use in patients with dementia-related psychosis.

Please see additional Important Safety Information throughout and the full Prescribing Information for WELTRUZA, including Boxed WARNING.

WELTRUZA™
(olanzapine) For extended-release injectable suspension
318mg 425mg 531mg

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

- **Post-Injection Delirium/Sedation Syndrome (PDSS)** has been reported in <0.1% of intramuscular injections of another extended-release olanzapine product. PDSS presented with signs and symptoms consistent with olanzapine overdose (eg, agitation, dysarthria, tachycardia, extrapyramidal symptoms, and sedation or coma). The majority of patients were hospitalized and some required supportive care, including intubation. The majority of cases occurred within the first 3 hours after injection. The risk of an event is the same at each injection, so the risk per patient is cumulative (i.e., increases with the number of injections).

  Healthcare professionals should consider PDSS in the differential diagnosis in the event a patient experiences the signs and symptoms of olanzapine overdose. In pre-marketing trials with WELTRUZA, there were no reported cases of PDSS. However, the risk of PDSS with WELTRUZA is currently unknown.

- **Cerebrovascular Adverse Reactions:** In placebo-controlled trials in elderly patients with dementia-related psychosis treated with oral risperidone, aripiprazole, or olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke compared to those treated with placebo. WELTRUZA is not approved for the treatment of patients with dementia-related psychosis.

- **Neuroleptic Malignant Syndrome (NMS):** NMS, a potentially fatal symptom complex, has been reported in association with antipsychotic drugs, including olanzapine. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If NMS is suspected, immediately discontinue WELTRUZA and provide intensive symptomatic treatment and monitoring.

- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** DRESS has been reported with exposure to olanzapine. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. DRESS is sometimes fatal. Discontinue WELTRUZA if DRESS is suspected.

- **Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. Metabolic changes may be associated with increased cardiovascular/cerebrovascular risk. Weight gain and changes in metabolic laboratory parameters were consistent with those expected with long-term olanzapine treatment. Olanzapine's specific metabolic profile, based on data from oral olanzapine, is presented below.

  - **Hyperglycemia and Diabetes Mellitus (DM):** in some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death, have been reported in patients treated with atypical antipsychotics (AAP), including olanzapine. While relative risk estimates are inconsistent, the association between AAP and increase in glucose levels appears to fall on a continuum, and olanzapine appears to have a greater association compared with some other AAPs. Physicians should consider the risks and benefits when prescribing WELTRUZA to patients with an established diagnosis of DM or with a borderline increase in blood glucose levels. Patients taking WELTRUZA should be monitored regularly for worsening of glucose control. Patients starting treatment with WELTRUZA should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. In some cases, hyperglycemia resolved when the AAP was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of olanzapine.

  - **Dyslipidemia:** Undesirable alterations in lipids have been observed with olanzapine use. Clinical monitoring, including baseline and periodic follow-up lipid evaluations in patients using WELTRUZA, is recommended. Clinically significant, and sometimes very high (≥500 mg/dL), elevations in triglyceride levels have been observed with olanzapine use.

  - **Weight Gain:** Potential consequences of weight gain should be considered prior to starting WELTRUZA. Patients receiving WELTRUZA should receive regular monitoring of weight.

- **Tardive Dyskinesia (TD):** TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs, including WELTRUZA. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop TD. Whether antipsychotic drug products differ in their potential to cause TD is unknown.

  The risk of developing TD and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the cumulative dose. The syndrome can develop, after relatively brief treatment periods, even at low dosages. It may also occur after discontinuation. TD may remit partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has on the long-term course of the syndrome is unknown.

  If signs and symptoms of TD appear in a patient treated on olanzapine, drug discontinuation should be considered. However, some patients may require treatment with olanzapine despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

- **Orthostatic Hypotension and Syncope:** WELTRUZA may induce orthostatic hypotension associated with dizziness, tachycardia, bradycardia, and in some patients, syncope. Olanzapine should be used with particular

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IMPORTANT SAFETY INFORMATION CONTINUED)

caution in patients with known cardiovascular disease, cerebrovascular disease, and conditions that would predispose patients to hypotension.

- **Falls:** Antipsychotics, including WELTRUZA, may cause somnolence, postural hypotension, motor and sensory instability which may lead to falls and, consequently, fractures or other injuries. If patients have a condition or take concomitant drugs that could exacerbate these effects, complete fall risk assessments when initiating treatment with WELTRUZA and recurrently for patients on long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis:** have been reported with antipsychotics, including olanzapine. Patients with a history of a clinically significant low white blood cell (WBC) count or drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy, and discontinuation of WELTRUZA should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000 mm^3) should discontinue WELTRUZA and have their WBC followed until recovery.
- **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's disease. Olanzapine is not approved for the treatment of patients with Alzheimer's disease.
- **Seizures:** Like other antipsychotic drugs, WELTRUZA may cause seizures. This risk is greatest in patients with a history of seizures or with conditions that lower the seizure threshold and WELTRUZA should be used cautiously. Conditions that lower the seizure threshold may be more prevalent in older patients.
- **Potential for Cognitive and Motor Impairment:** WELTRUZA, like other antipsychotics, may cause somnolence and has the potential to impair judgement, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that WELTRUZA does not affect them adversely.
- **Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing WELTRUZA for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.
- **Anticholinergic Effects:** Olanzapine exhibits in vitro muscarinic receptor affinity. In premarketing clinical trials, oral olanzapine was associated with constipation, dry mouth, and tachycardia, all adverse reactions possibly related to cholinergic antagonism. WELTRUZA should be used with caution in patients with a current diagnosis or prior history of urinary retention, clinically significant prostatic hypertrophy, constipation, or a history of paralytic ileus or related conditions. In postmarketing experience, the risk for severe adverse reactions (including fatalities) was increased with concomitant use of anticholinergic medications.
- **Hyperprolactinemia:** As with other drugs that antagonize dopamine receptors, olanzapine elevates prolactin levels, and the elevation persists during chronic administration. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

ADVERSE EVENTS

Most common adverse reactions (≥5% in at least one of the treatment groups and greater than placebo) associated with WELTRUZA treatment: weight increased, somnolence, headache, constipation, and injection site reactions (induration, pain, erythema, pruritus, swelling).

DRUG INTERACTIONS

- Strong CYP1A2 or Glucuronyl Transferase Inducers: Concomitant use may decrease olanzapine exposure; monitor for lack of symptom control and consider dosage increase of WELTRUZA
- Strong CYP1A2 Inhibitors: Consider dosage reduction of WELTRUZA when administered concomitantly with strong CYP1A2 Inhibitors
- Centrally-Acting Drugs and Alcohol: May potentiate orthostatic hypotension.
- CNS Acting Drugs: Caution should be used when used in combination with other centrally acting drugs and alcohol.
- Antihypertensive Agents: Enhanced antihypertensive effect.
- Levodopa and Dopamine Agonists: May antagonize levodopa/dopamine agonists.
- Anticholinergic Drugs: Can increase the risk for severe gastrointestinal adverse reactions related to hypomotility

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Use only if the potential benefit justifies the potential risk to the fetus. WELTRUZA may cause extrapyramidal symptoms (EPS) and/or withdrawal symptoms in neonates with third-trimester exposure. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics, including WELTRUZA, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for AAPs at 1-866-961-2388 or online at http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.
- **Lactation:** WELTRUZA is present in human milk. Infants should be monitored for excess sedation, irritability, poor feeding, and extrapyramidal symptoms (tremors and abnormal muscle movements).
- **Fertility:** WELTRUZA may cause a reversible reduction in fertility in females.
- **Pediatric Use:** Safety and effectiveness of WELTRUZA in pediatric patients have not been established.

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KEEPING WELTRUZA™ READY

Store WELTRUZA in a refrigerator at 2 °C to 8 °C (36 °F to 46 °F) **in the original carton.**

Unopened WELTRUZA may be stored at room temperature, **20 °C to 25 °C** (68 °F to 77 °F), for a single period of up to 90 days.

If you haven't used WELTRUZA after 90 days at room temperature, dispose of it and talk to your Teva representative about product replacement.

People featured are not actual patients, caregivers, or doctors.

Need instructions for administering WELTRUZA?

Refer to the Instructions for Use in the **Prescribing Information**.
Visit **WELTRUZAhcp.com**

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References: 1. WELTRUZA™ (olanzapine) extended-release injectable suspension Current Prescribing Information. Parsippany, NJ: Teva Neuroscience, Inc. **2.** Alavi M, Ridout SJ, Lee C, Harris B, Ridout KK. Schizophr Bull Open. 2024;5(1):sgae01 1. **3.** Data on file. Clinical Study Report. November 2025. West Chester, PA: Teva Neuroscience, Inc.

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