



## INDICATIONS & IMPORTANT SAFETY INFORMATION

### INDICATIONS:

FazaClo is indicated for (1) the management of severely ill patients with schizophrenia who fail to respond adequately to standard drug treatment, and (2) reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder.

Phenylketonurics: FazaClo Orally Disintegrating Tablets contain phenylalanine.

### IMPORTANT SAFETY INFORMATION:

#### Boxed Warnings

**Agranulocytosis** (a drop in white blood cell levels) is a serious side effect associated with clozapine therapy. Due to the risk of agranulocytosis, clozapine should be reserved for (1) severely ill patients with schizophrenia who fail to respond adequately to standard drug treatment, or (2) patients with schizophrenia or schizoaffective disorder at risk of recurrent suicidal behavior. Patients being treated with clozapine must have their blood tested for a baseline white blood cell (WBC) count and absolute neutrophil count (ANC) before initiation of treatment, and have regular WBC counts and ANCs during treatment and for at least 4 weeks after discontinuation of treatment. You should immediately report to your health professionals any feelings of slowing down, weakness, fever, sore throat, sick feelings, mouth sores, flu-like complaints, or other possible signs of infection.

**Myocarditis** is a type of inflammation of the heart muscle. Analyses of post-marketing safety databases suggest that clozapine is associated with an increased risk of fatal myocarditis, especially during the first month of therapy. In patients in whom myocarditis is suspected, clozapine treatment should be promptly discontinued. If you experience fatigue, rapid breathing, are easily out of breath, or have periods of sudden rapid heart beats, report these symptoms to your health professionals immediately.

**Seizures** have been associated with clozapine, with a greater likelihood at higher doses. People who have a history of seizures are also more likely to experience seizures with FazaClo therapy. Patients should avoid driving and any other hazardous activities while taking this medication.

**Orthostatic hypotension**, a rapid drop in blood pressure that makes you feel faint or dizzy, with or without collapse, can occur with clozapine treatment. Rarely, collapse can be profound and be accompanied by respiratory and/or cardiac arrest. Orthostatic hypotension is more likely to occur during initial dosing, in association with a rapid dose escalation.

**Elderly patients** with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. FazaClo is not approved for the treatment of those patients.

**CONTRAINDICATIONS (situations where FazaClo should not be prescribed):** FazaClo is contraindicated in patients with myeloproliferative disorders, uncontrolled epilepsy, paralytic ileus, history of clozapine-induced agranulocytosis or severe granulocytopenia, and in severe central nervous system (CNS) depression or comatose states from any cause. FazaClo should not be used simultaneously with other agents having a well-known potential to cause agranulocytosis or otherwise suppress bone marrow function.

**WARNINGS: Neuroleptic Malignant Syndrome (NMS)**, a potentially fatal symptom complex has been reported in association with antipsychotic drugs. Symptoms of NMS are high fever, muscle rigidity, and altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia) diaphoresis (sweating), and cardiac dysrhythmias (rapid or irregular heart beat).

**Tardive dyskinesia**, a syndrome consisting of potentially irreversible, involuntary, dyskinetic (twitching, jerky, involuntary) movements may develop in patients treated with antipsychotic drugs. There have been no reports of tardive dyskinesia directly attributable to clozapine alone. Nevertheless, it cannot be concluded without more extended experience that FazaClo is incapable of inducing this syndrome.

**Hyperglycemia (high blood sugar)**, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including clozapine. Patients with an established diagnosis of diabetes mellitus initiating atypical antipsychotics should be monitored regularly for worsening of glucose control, and patients with risk factors for diabetes mellitus should undergo fasting blood glucose testing upon initiation of and periodically during treatment with atypical antipsychotics. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia.

**Commonly occurring adverse events reported with clozapine** are excess saliva, sedation, weight gain, dizziness, constipation and tachycardia.