

Understanding Your New Prescription for FazaClo® (clozapine, USP)

Your FazaClo medication will be changing soon, to help give you the therapy you need in a more convenient way

- FazaClo now has higher-dose pills, so you can get the same amount of medicine you usually take, with fewer pills
- **Do not worry:**
 - There will be no change to the taste or color of your medicine
 - The medicine works the same way and should be taken as your doctor prescribes

| Your New FazaClo Prescription | | |
|--|-----------------------------|---|
| <u>THEN</u> Before, you took | _____ FazaClo pills per day | _____ pills in the morning and _____ pills in the evening |
| <u>NOW</u> You will now take | _____ FazaClo pills per day | _____ pills in the morning and _____ pills in the evening |

You may now receive your orally dissolving FazaClo prescription in any combination of these dose strengths:

Actual sizes



12.5 mg



25 mg



100 mg



150 mg



200 mg

Talk to your healthcare provider if you have any questions or concerns about your FazaClo prescription.

Important Safety Information

Phenylketonurics: FazaClo® Orally Disintegrating Tablets contain phenylalanine.

BOXED WARNINGS: Due to the high risk of low white blood cell count (WBC), clozapine should only be taken by (1) severely ill patients with schizophrenia who do not respond to standard drug treatment or (2) patients with schizophrenia or schizoaffective disorder at risk of repeated suicidal behavior. Before patients start clozapine therapy, they should ask their doctor about their WBC count, absolute neutrophil count (ANC), and clinical monitoring schedule.

(continued on back)

Please see continuation of Risk Information and Important Safety Information on back.

BOXED WARNINGS: (continued)

Clozapine also causes an increased risk of seizures when taking higher doses, inflammation of the heart, low blood pressure with or without fainting, as well as respiratory and/or cardiac arrest associated with the use of other drugs. Check with a doctor to make sure there are no interactions with clozapine and other medications the patient is taking. Elderly patients with memory-related psychosis are at a greater risk of death.

INDICATIONS: FazaClo® is indicated for (1) managing severely ill schizophrenic patients who do not respond to standard drug treatment, and (2) reducing the risk of repeated suicidal behavior in patients with schizophrenia or schizoaffective disorder.

CONTRAINDICATIONS: FazaClo is contraindicated in patients with blood cancers, uncontrolled epilepsy, partial or complete blockage of the bowel, history of clozapine related low WBC count, and in severe central nervous system (CNS) depression. FazaClo should not be taken if a patient has had an allergic reaction to clozapine or any other ingredient of this drug. Check with a doctor to make sure there are no interactions with clozapine and other medications the patient is taking.

WARNINGS: A possibly deadly symptom complex also known as Neuroleptic Malignant Syndrome (NMS) has been reported with the use of antipsychotic drugs. Warning signs may include: high fever, muscle stiffness, a change in mental state, irregular blood pressure, fast heart rate, intense sweating, and irregular heart rate.

Tardive dyskinesia, a syndrome consisting of possibly permanent, uncontrolled, movements, may develop in patients taking antipsychotic drugs. There have been no reports of this syndrome in patients taking only clozapine. However, it cannot be determined without more experience that FazaClo is unable to induce this syndrome.

High blood sugar, in some cases extreme and associated with coma or death, has been reported in patients treated with atypical antipsychotics including clozapine. Patients should check with a doctor to make sure their sugar is monitored when starting treatment and throughout drug therapy with clozapine.

For additional information, including full prescribing information, please call **1-877-FAZACLO (329-2256)** or log on to **www.fazaclo.com**.

