**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use VERSACLOZ®. See full prescribing information for details.

**INDICATIONS AND USAGE**

VERSACLOZ is an atypical antipsychotic indicated for:

**Titration:** increase the total daily dosage in increments of 25 mg to 50 mg per day, if well-tolerated (2.2).

**CONTRAINDICATIONS**

Do not use VERSACLOZ in patients who have had Neutropenia or infections with neutrophil counts less than 1500/µL at initial treatment with VERSACLOZ or during treatment with VERSACLOZ. Do not use VERSACLOZ in patients who have had baseline neutropenia.

**WARNINGS AND PRECAUTIONS**

**Hyperglycemia and Diabetes Mellitus:**

- Monitor patients with diabetes closely and discontinue VERSACLOZ if severe hyperglycemia develops. Monitor glucose regularly in patients with diabetes or at risk for diabetes (5.10).

**Cardiac Effects:**

- Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with clozapine (5.6).

**Neutropenia:**

- Treating patients with neutropenia (ANC < 1500/µL) is associated with an increased risk of death (2.2 and 5.7).

**Neuroleptic Malignant Syndrome (NMS):**

- NMS is a rare but very serious problem. Discontinue VERSACLOZ if NMS is suspected (5.7).

**Oncologic Patients:**

- Use caution when administering concomitant medications that prolong the QT interval or inhibit the metabolism of VERSACLOZ (5.8). Use caution when administering concomitant medications that cause QT prolongation, treatment with medications that inhibit the metabolism of VERSACLOZ, and strong CYP1A2 inhibitors (5.8).

**Optical Displacement:**

- Use one third of the VERSACLOZ dose for patients who are taking Strong CYP1A2 Inhibitors (5.8).

**Clozapine Titration:**

- Start with the initial daily dose of 25 mg and increase as tolerated (4.1).

**Skin Reactions:**

- Profound skin reactions have occurred with clozapine (5.14).

**Sedation:**

- Some patients experience sedation (5.17).

**Liver Transaminase Elevations:**

- Liver transaminase elevations have occurred with clozapine (5.16).

**Weight Gain:**

- Weight gain is a known side effect of clozapine (5.3).

**Agranulocytosis:**

- Use caution when using VERSACLOZ in patients who have a history of agranulocytosis (5.7).

**Diabetes:**

- Monitor patients with diabetes or at risk for diabetes (5.10).

**Hypothyroidism:**

- Monitor thyroid function (5.10).

**CYP1A2 Inhibitors:**

- Use one third of the VERSACLOZ dose for patients who are taking Strong CYP1A2 Inhibitors (5.8).

**Drug Interactions:**

- Use caution when administering concomitant medications that inhibit the metabolism of VERSACLOZ (5.8).

**Lactation:**

- Nursing mothers should avoid breastfeeding if treated with VERSACLOZ (5.9).

**Neutropenia:**

- Neutropenia is a side effect of VERSACLOZ (5.7).

**ADVERSE REACTIONS**

**Most common adverse reactions**

- See full prescribing information for a complete list of adverse reactions.

**Laboratory Test Changes**

- Changes in laboratory tests, including electrocardiogram (ECG) parameters, have occurred (2.2). Changes in liver function tests, blood chemistry tests, and ECG parameters were the most common laboratory test changes occurring during treatment (2.2).

**INFORMATION FOR PATIENTS**

- VERSACLOZ can be taken with or without food (5.11).

**PATIENT FOCUS**

- VERSACLOZ can be used to treat schizophrenia in adults (5.11).

**HOW SUPPLIED/STORAGE AND HANDLING**

- VERSACLOZ is available in a 60-mL amber-colored plastic bottle with a tamper-evident closure and a child-resistant cap. The bottle contains a pump that delivers 60 mg per 15 mL. The pump contains a syringe, syringe adaptor, and patient instructions for use (5.11).

**DOSE AND ADMINISTRATION**

- VERSACLOZ is available in a 60-mL amber-colored plastic bottle with a tamper-evident closure and a child-resistant cap. The bottle contains a pump that delivers 60 mg per 15 mL. The pump contains a syringe, syringe adaptor, and patient instructions for use (5.11).

**LIMITATIONS OF USE**

- VERSACLOZ is not a cure for schizophrenia (5.11).

**DOSAGE FORMS AND STRENGTHS**

- VERSACLOZ is available in a 60-mL amber-colored plastic bottle with a tamper-evident closure and a child-resistant cap. The bottle contains a pump that delivers 60 mg per 15 mL. The pump contains a syringe, syringe adaptor, and patient instructions for use (5.11).

**PATIENT INFORMATION**

- VERSACLOZ can be used to treat schizophrenia in adults (5.11).

**ADMINISTRATION**

- VERSACLOZ can be taken with or without food (5.11).

**SIDE EFFECTS**

- Side effects, such as sedation, can occur (5.17).

**PATIENT FOCUS**

- VERSACLOZ can be used to treat schizophrenia in adults (5.11).

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**ADMINISTRATION**

- VERSACLOZ can be taken with or without food (5.11).

**SIDE EFFECTS**

- Side effects, such as sedation, can occur (5.17).
Do not give VERSACLOZ to other people, even if they have the same symptoms that you have.

Step 6

If your dose is 1 mL (50 mg) or less

Instructions

Fill the oral syringe with air by drawing back the plunger and draw the water into the oral syringe.

Remove the oral syringe from the bottle neck adaptor so the liquid goes into your mouth. Swallow.