

**MEDICATION GUIDE**  
**VERSACLOZ\* (VER sa kloz)**  
**(clozapine)**  
**oral suspension**

**What is the most important information I should know about VERSACLOZ?**  
**VERSACLOZ can cause serious side effects, including:**

- **Severe neutropenia (low white blood cell (WBC) counts) that can lead to serious infections and death.** Your healthcare provider will do WBC blood tests before starting treatment with VERSACLOZ and weekly for the first 6 months. After your first 6 months of treatment, your healthcare provider will determine how frequent you will have blood tests. If you have symptoms of severe neutropenia or an infection, your healthcare provider will do more frequent WBC blood test(s) to check if VERSACLOZ is causing your symptoms and may send you to see a blood specialist (hematologist). Tell your healthcare provider right away if you have any of the following symptoms or signs of neutropenia or infection:
  - feel like you have the flu
  - fever or chills
  - feel extremely tired or weak
  - sores or ulcers inside your mouth, gums, or on your skin
  - sores or pain in or around your rectal area
  - wounds that take a long time heal
  - skin, throat, vaginal, urinary tract, or lung infection
  - pain or burning while peeing
  - unusual vaginal discharge or itching
  - abdominal pain or bloating
- **Orthostatic hypotension (decreased blood pressure), bradycardia (slow heart rate), or syncope (fainting) that can lead to death.** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position. Tell your healthcare provider right away if you feel dizzy or pass out.
- **Seizures.** See “**What should I avoid while taking VERSACLOZ?**”
- **Myocarditis (heart muscle inflammation), pericarditis (inflammation of outer layer of the heart) and cardiomyopathy (heart muscle weakness) that can lead to death.** Symptoms of myocarditis, pericarditis, and cardiomyopathy include:
  - chest pain
  - fast heartbeat or palpitations
  - shortness of breath
  - fever
  - flu-like symptoms
  - feel tired or faint
  - swollen legs, ankles, or feet
- **Increased risk of death in elderly people with dementia-related psychosis.**

Medicines like VERSACLOZ can increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and dementia. VERSACLOZ is not for treatment of elderly people with dementia-related psychosis.

### **What is VERSACLOZ?**

VERSACLOZ is a prescription antipsychotic medicine used to treat people:

- Who are severely ill with schizophrenia not helped by other schizophrenia medicines
- With schizophrenia or schizoaffective disorder who have been suicidal and may be at risk of suicidal behavior again

It is not known if VERSACLOZ is safe and effective in children.

### **Who should not take VERSACLOZ?**

#### **Do not take VERSACLOZ if you:**

- are allergic to clozapine or any of the ingredients in VERSACLOZ. See the end of this Medication Guide for a complete list of ingredients in VERSACLOZ.

#### **Before taking VERSACLOZ, tell your healthcare provider about all your medical conditions, including if you:**

- have or have had heart problems or a family history of heart problems including heart attack, heart failure, abnormal heart rhythm or long QT syndrome, or stroke
- have or have had low or high blood pressure
- have or have had kidney or liver problems
- have or have had seizures (convulsions)
- have or have had stomach or intestinal problems including constipation, slow emptying of your stomach, or diarrhea
- have or have had low levels of potassium or magnesium in your blood
- have or have had diabetes or high blood sugar in you or your family
- have or have had high levels of total cholesterol, “bad” cholesterol (LDL-C), or triglycerides, or low levels of “good” cholesterol (HDL-C)
- have increased pressure in your eyes (glaucoma), an enlarged prostate, or problems passing urine
- have or have had uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)
- smoke tobacco
- plan to stop smoking tobacco while taking VERSACLOZ
- use products containing caffeine
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you become pregnant while taking VERSACLOZ.
  - If you become pregnant while receiving VERSACLOZ, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>
- are breast feeding or plan to breast feed. VERSACLOZ can pass into your breast

milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take VERSACLOZ.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- VERSACLOZ and other medicines may affect each other causing side effects.
- Your healthcare provider can tell you if it is safe to take VERSACLOZ with your other medicines. Do not start or stop any medicines while taking VERSACLOZ without talking to your healthcare provider first.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

### **How should I take VERSACLOZ?**

- Take VERSACLOZ exactly as your healthcare provider tells you to take it. **Do not** change your dose or stop taking VERSACLOZ unless your healthcare provider tells you to. Talk to your healthcare provider or pharmacist if you are not sure how to take VERSACLOZ.
- Take VERSACLOZ with or without food.
- If your healthcare provider decides that you can take VERSACLOZ at home, you should receive training on the correct way to take VERSACLOZ. **Do not** try to take VERSACLOZ yourself until you have been shown how to take VERSACLOZ.
- See the detailed **Instructions for Use** at the end of this Medication Guide for information on how to take VERSACLOZ.
- If you miss taking VERSACLOZ for 1 day or more, call your healthcare provider right away. Do not take 2 doses at the same time unless your healthcare provider tells you to.
- If you take too much (overdose) VERSACLOZ, call your healthcare provider or the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

### **Symptoms of VERSACLOZ overdose can include:**

- feeling sleepy
- fast or irregular heartbeat
- having a lot of saliva in your mouth
- confusion
- low blood pressure
- seizures
- coma
- shallow or difficult breathing

### **What should I avoid while taking VERSACLOZ?**

- You should not drink alcohol while taking VERSACLOZ because it can increase your chances of getting serious side effects.
- Do not drive, operate machinery, swim, climb, or do dangerous activities until you know how VERSACLOZ affects you.

## What are the possible side effects of VERSACLOZ?

**VERSACLOZ may cause serious side effects, including:**

- See "**What is the most important information I should know about VERSACLOZ?**"
- **falls.** VERSACLOZ may make you sleepy, dizzy, may cause a decrease in your blood pressure when changing positions, and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.
- **slow emptying of your stomach and intestines (decreased gastric motility). Severe constipation and bowel problems can happen and can lead to hospitalization, surgery, and death.** You may not feel or be aware of constipation symptoms. Your healthcare provider will examine you for possible bowel problems. Tell your healthcare provider if you get any signs and symptoms of decreased gastrointestinal motility during treatment with VERSACLOZ, including:
  - having bowel movements less than normal
  - hard or dry stools
  - difficulty in passing gas
  - stomach bloating or pain
  - nausea or vomiting

Staying well hydrated, increasing physical activity, and taking fiber during treatment with VERSACLOZ can help prevent constipation and other bowel problems. Your healthcare provider may prescribe medicines to prevent severe problems.

- **high count of a certain white blood cell (eosinophilia).** VERSACLOZ can cause a high count of eosinophils in some people and can be serious. This is a different risk than the risk of VERSACLOZ causing an abnormally low white blood cell count (neutropenia). Your healthcare provider may send you to see an internal medicine specialist (internist) or blood specialist (hematologist). Tell your healthcare provider right away if you have any of these symptoms:
  - feeling very tired or weak
  - fever
  - rash
  - swelling
  - joint pain
  - coughing and wheezing
  - nausea, vomiting, or diarrhea
  - night sweats
  - confusion
  - difficulty swallowing
- **serious heart rhythm problems (QTc Interval Prolongation) that can cause death.** Your healthcare provider will do a physical exam and may obtain blood tests and an electrocardiogram before starting you on treatment with VERSACLOZ. Tell your healthcare provider right away if you have any of these symptoms:
  - passing out or feeling like you will pass out
  - dizziness
  - feeling as if your heart is pounding or missing beats

- **problems with your metabolism such as:**
  - **high blood sugar (hyperglycemia) or diabetes.** Increases in blood sugar can happen in some people who take VERSACLOZ. Extremely high blood sugar can lead to coma and death. If you have diabetes or risk factors for diabetes (such as being overweight), your healthcare provider should check your blood sugar before you start VERSACLOZ and during treatment. Tell your healthcare provider if you have any of these symptoms of high blood sugar while taking VERSACLOZ:
    - feel very thirsty
    - feel very hungry
    - feel sick to your stomach
    - need to urinate more than usual
    - feel weak or tired
    - feel confused, or your breath smells fruity
  - **increased fat levels (cholesterol and triglycerides) in your blood (dyslipidemia).** Your healthcare provider should check the fat levels in your blood before you start and during treatment with VERSACLOZ.
  - **weight gain.** You and your healthcare provider should check your weight regularly.
- **neuroleptic malignant syndrome (NMS).** NMS is a rare but serious condition that can lead to death and must be treated in a hospital. Tell your healthcare provider right away if you become severely ill and have any of these symptoms:
  - high fever
  - confusion
  - increased sweating
  - stiff muscles
  - changes in breathing, heartbeat, and blood pressure
- **liver problems.** VERSACLOZ can cause serious life-threatening liver problems that can lead to death. Tell your healthcare provider right away if you have any of these symptoms:
  - feeling tired
  - nausea and vomiting
  - pain on the right side of your stomach (abdomen)
  - loss of appetite
  - yellowing of your skin or whites of your eyes
  - elevated bilirubin levels
- **fever.** Some people may have a fever while they take VERSACLOZ. If you have a fever, your healthcare provider will do blood tests to check for neutropenia or an infection. Your healthcare provider may also send you to see a blood specialist (hematologist). Tell your healthcare provider if you have a fever.
- **blood clot in your lung (pulmonary embolism) or in the veins of your legs (deep vein thrombosis).** Get emergency help right away if you have symptoms of a blood clot including:
  - chest pain and shortness of breath
  - swelling or pain in your leg, ankle or foot
  - warm feeling in the skin of your affected leg
  - changes in your skin color such as turning pale or blue

- **a problem that includes dry mouth, increased sweating, increased pulse rate, constipation, and urinary retention (anticholinergic toxicity).**
- **problems thinking clearly and moving your body. See “What should I avoid while taking VERSACLOZ?”**
- **uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia).** Tardive dyskinesia may not go away, even if you stop VERSACLOZ. Tardive dyskinesia may also start after you stop taking VERSACLOZ.
- **stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**

**The most common side effects of VERSACLOZ include:**

- |                                   |  |
|-----------------------------------|--|
| • sleepiness or drowsiness        | • headache                             |
| • dizziness                       | • shaking movements (tremors)          |
| • heart and blood vessel problems | • low blood pressure                   |
| • fast heartbeat                  | • having a lot of saliva in your mouth |
| • passing out (syncope)           | • dry mouth                            |
| • increased sweating              | • constipation and nausea              |
| • vision problems                 | • fever                                |
- These are not all the possible side effects of VERSACLOZ.
  - Your healthcare provider may lower your dose or temporarily or permanently stop treatment with VERSACLOZ if you have certain symptoms or if your WBC count is low.
  - Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
  - You may report side effects to FDA at 1-800-FDA-1088.

**How should I store VERSACLOZ?**

- Store VERSACLOZ at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate VERSACLOZ.
- Do not freeze VERSACLOZ.
- Keep the VERSACLOZ bottle in the carton to protect it from light.
- Throw away (discard) any unused VERSACLOZ oral suspension remaining after 100 days of first opening the bottle.

**Keep VERSACLOZ and all medicines out of the reach of children.**

**General information about the safe and effective use of VERSACLOZ**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VERSACLOZ for a condition for which it was not prescribed. Do not give VERSACLOZ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider (including pharmacist) for information about VERSACLOZ that is written for

healthcare professionals.

**What are the ingredients in VERSACLOZ?**

**Active ingredient:** clozapine

**Inactive ingredients:** glycerin, sorbitol (crystallizing), sodium dihydrogen phosphate dihydrate, xanthan gum, sodium methylparaben, sodium propylparaben, povidone, water, and sodium hydroxide

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For optional information, go to [www.VERSACLOZ.com](http://www.VERSACLOZ.com) or call 1-800-520-5538.

This Medication Guide has been approved by the U.S. Food and Drug Administration.  
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