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Versacloz

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 - **DosageForm:**
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 - **Indications:**
 - **Manufacturer:**
 - **Storage:**
 - **Market Price:**
 - **Drug Status:**
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Description

Side Effects Drooling, drowsiness, dizziness, lightheadedness, headache, shaking (tremor), vision problems (such as blurred vision), constipation, and weight gain may occur. Many of these effects (especially drowsiness) lessen as your body gets used to the medication. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To prevent constipation, eat dietary fiber, drink enough water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. This medication may rarely make your blood sugar rise, which can cause or worsen diabetes. Tell your doctor right away if you have symptoms of high blood sugar such as increased thirst/urination. If you already have diabetes, check your blood sugar regularly as directed and share the results with your doctor. Your doctor may need to adjust your diabetes medication, exercise program, or diet. This drug may also cause significant weight gain and a rise in your cholesterol (or triglyceride) levels. These effects, along with diabetes, may increase your risk for developing heart disease. Discuss the risks and benefits of treatment with your doctor. Tell your doctor right away if you have any serious side effects, including: facial/muscle twitching, seizures, uncontrollable movements, interrupted breathing during sleep, trouble urinating, severe constipation. Get medical help right away if you have any very serious side effects, including: nausea/vomiting that doesn't stop, severe dizziness, fainting, mental/mood changes, difficulty breathing with exercise, sudden weakness, pain/redness/swelling of the arms/legs, stomach/abdominal pain, yellowing of eyes/skin. This medication may rarely cause a very serious condition called neuroleptic malignant syndrome (NMS). Get medical help right away if you have any of the following symptoms: fever, muscle stiffness/pain/tenderness/weakness, severe tiredness, severe confusion, sweating, fast/irregular heartbeat, dark urine, signs of kidney problems (such as change in the amount of urine). A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. How long does it take for this medicine to take effect? The onset of therapeutic effects of clozapine can vary significantly among

individuals. Some patients may begin to notice improvements in their symptoms within the first few weeks of treatment, but full therapeutic benefits may take several months to develop. The initial effects often include sedation and a reduction in agitation. How long do the effects of this medicine last? Clozapine's effects are sustained with continuous use. The medication is typically prescribed for long-term management of schizophrenia symptoms, and consistent daily dosing is necessary to maintain its therapeutic benefits. The half-life of clozapine is about 12 to 16 hours, requiring twice-daily dosing to maintain steady blood levels. Is it safe to consume alcohol while taking this medicine? Consuming alcohol while taking clozapine is not recommended. Alcohol can exacerbate clozapine's central nervous system depressant effects, increasing the risk of sedation, dizziness, and impairing cognitive and motor skills. Additionally, alcohol use can worsen the side effects of clozapine, including seizures and orthostatic hypotension (a drop in blood pressure upon standing). Is this a habit forming medicine? Clozapine is not considered habit-forming and does not have a high potential for abuse or dependence. However, it is critical for patients to use this medication under strict medical supervision due to its risk profile, including the potential for severe side effects. Can this medicine be taken during pregnancy? Clozapine is classified as FDA Pregnancy Category B, indicating that animal reproduction studies have not demonstrated a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Clozapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and it should be prescribed with caution after careful consideration of the risks and benefits. Can this medicine be taken while breast-feeding? Clozapine is excreted into breast milk, and there is potential for adverse effects on the nursing infant. Given the risk of serious side effects, including sedation and potential hematological abnormalities, breastfeeding is not recommended while taking clozapine. The decision to continue or discontinue either clozapine or breastfeeding should be made in consultation with a healthcare provider, considering the importance of the medication to the mother's health.

Uses This medication is used to treat certain mental/mood disorders (schizophrenia, schizoaffective disorders). Clozapine is a psychiatric medication (anti-psychotic type) that works by helping to restore the balance of certain natural substances (neurotransmitters) in the brain. Clozapine decreases hallucinations and helps prevent suicide in people who are likely to try to harm themselves. It helps you to think more clearly and positively about yourself, feel less nervous, and take part in everyday life.

How to use Versacloz If you are using the liquid form of this medication, read the Patient Information Leaflet if available from your pharmacist before you start taking clozapine and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with or without food, as directed by your doctor. If you are taking the tablets that dissolve in the mouth, carefully remove each tablet from the blister pack immediately before taking your dose. Allow the tablets to dissolve on your tongue and swallow. You do not need to take the dissolving tablets with water. Discard any dissolving tablets that have been previously exposed to air due to opened/damaged packaging. Do not save them for your next dose. If you are using the liquid form of this medication, shake the bottle well for 10 seconds before each use. Carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose. It is important to begin taking this drug at a low dose, increasing your dose slowly, to lessen side effects such as dizziness, drowsiness and seizures. Follow your doctor's instructions exactly. Your dosage is based on your medical condition and response to therapy. Since clozapine can cause a decrease in white blood cells, you will need to get blood tests done regularly as directed. Be sure to keep all appointments for these lab tests. () If you miss your doses for longer than a day or two, consult your doctor for a new schedule to get back to the dose you were on (see Missed Dose section). Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time(s) each day. Do not stop taking clozapine without consulting your doctor. Some conditions may become worse when the drug is suddenly stopped. Also, you may experience symptoms such as severe sweating, headache, nausea, vomiting, and diarrhea. To prevent these symptoms while you are stopping treatment with this drug, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details. Report any new or worsening symptoms right away. It may take several weeks before the full benefit of this drug takes effect. Tell your doctor if your condition lasts or gets worse.

Warnings While clozapine can provide great benefits, it can rarely cause serious, possibly fatal side effects. For this reason, clozapine is used when other treatments have not worked or you cannot take them. To receive this medication in the United States, you must understand, agree to, and carefully follow the requirements of the Clozapine REMS Program. If you live in Canada or any other country, consult your doctor and pharmacist for your country's regulations. This

medication can cause a serious decrease of a certain type of white blood cells (neutropenia). To make sure you have enough white blood cells, your doctor will order lab tests before starting and while you are taking clozapine. Neutropenia may lower your ability to fight infections. Get medical help right away if you have any signs of severe neutropenia or infection (such as sore throat that doesn't go away, fever, swollen lymph nodes, unusual tiredness, weakness). Clozapine can also cause seizures, especially in higher doses. Let your doctor or pharmacist know if you have ever had seizures. While taking this medication, avoid driving or other activities during which a sudden loss of consciousness could be dangerous (such as operating heavy machinery, swimming). This medication may rarely cause an inflammation of the heart muscle (myocarditis) or heart failure. Get medical help right away if you develop chest pain, fast/irregular heartbeat, shortness of breath, swelling ankles/feet, unusual tiredness, or unusual/sudden weight gain. Clozapine can cause low blood pressure or a slow heartbeat, which can make you dizzy or cause you to faint when you stand up. The risk is higher when you first start or increase your dose of medication. Dizziness and lightheadedness can increase the risk of falling. Get up slowly when rising from a sitting or lying position. There may be a slightly increased risk of serious, possibly fatal side effects (such as stroke, heart failure, fast/irregular heartbeat, pneumonia) when this medication is used by older adults with dementia. This medication is not approved for the treatment of dementia-related behavior problems. Discuss the risks and benefits of this medication, as well as other effective and possibly safer treatments for dementia-related behavior problems, with the doctor.

Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. A product that may interact with this drug is: metoclopramide. Other medications can affect the removal of clozapine from your body, which may affect how clozapine works. Examples include fluvoxamine, saquinavir, St. John's wort, drugs used to treat seizures (such as carbamazepine, phenytoin), among others. Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely. Cigarette smoking decreases blood levels of this medication. Tell your doctor if you smoke or if you have recently stopped smoking.

Precautions Before taking clozapine, tell your doctor or pharmacist if you are allergic to it or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: history of blood disorders (such as leukemia, low white blood cell count), bowel problems (such as paralytic ileus, irritable bowel syndrome), breathing problems, diabetes/family history of diabetes, high cholesterol/triglyceride levels, glaucoma, heart problems, kidney problems, liver problems, obesity/family history of obesity, seizures, difficulty urinating (for example, due to enlarged prostate), breathing trouble during sleep (sleep apnea). Clozapine may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may affect the heart rhythm. Before using clozapine, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using clozapine safely. This drug may make you dizzy or drowsy or blur your vision. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness or clear vision until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Tell your doctor if you are a descendent of Ashkenazi Jews because you may be at a higher risk for a drop in your white blood cells. Before having surgery, tell your doctor or dentist about all the products you use

(including prescription drugs, nonprescription drugs, and herbal products). Liquid products or dissolving tablets may contain sugar and/or aspartame. Liquid products may also contain alcohol. Caution is advised if you have diabetes, liver disease, phenylketonuria (PKU), or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely. Older adults may be more sensitive to the side effects of this drug, especially constipation, trouble urinating, drowsiness, dizziness, lightheadedness, and QT prolongation (see above). Drowsiness, dizziness, and lightheadedness can increase the risk of falling. During pregnancy, this medication should be used only when clearly needed. Babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop symptoms including muscle stiffness or shakiness, drowsiness, feeding/breathing difficulties, or constant crying. If you notice any of these symptoms in your newborn especially during their first month, tell the doctor right away. Since untreated mental/mood problems (such as schizophrenia, schizoaffective disorders) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy. This medication may pass into breast milk and have undesirable effects on a nursing infant. Breast feeding is not recommended while taking clozapine. Consult your doctor before breast-feeding. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Do not share this medication with others. Lab and/or medical tests (such as complete blood count, liver function, blood sugar, weight, cholesterol/triglyceride levels) must be done before you start taking this medication and while you are taking it. Clozapine blood levels may also be checked. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. If you miss doses for longer than a day or two, consult your doctor for a new schedule to get back to the dose you were taking. Do not double the dose to catch up. Store at room temperature away from light and moisture. Store the dissolving tablets in their blister packets, and do not remove each dose until just before taking. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Side Effects

Uses

Interactions

Other Details
