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Clozapine

pronounced as (kloe' za peen)

IMPORTANT WARNING:

Clozapine can cause a serious blood condition. Your doctor will order certain lab tests before you start your treatment, during your treatment, and for at least 4 weeks after your treatment. Your doctor will order the lab tests once a week at first and may order the tests less often as your treatment continues. If you experience any of the following symptoms, call your doctor immediately: extreme tiredness; weakness; fever, sore throat, chills, or other signs of flu or infection; unusual vaginal discharge or itching; sores in your mouth or throat; wounds that take a long time to heal; pain or burning while urinating; sores or pain in or around your rectal area; or abdominal pain.

Because of the risks with this medication, clozapine is available only through a special restricted distribution program. A program has been set up by the manufacturers of clozapine to be sure that people do not take clozapine without the necessary monitoring called the Clozapine Risk Evaluation and Mitigation Strategies (REMS) Program. Your doctor and your pharmacist must be registered with the Clozapine REMS program, and your pharmacist will not dispense your medication unless he or she has received the results of your blood tests. Ask your doctor for more information about this program and how you will receive your medication.

Clozapine may cause seizures. Tell your doctor if you have or have ever had seizures. Do not drive a car, operate machinery, swim, or climb while taking clozapine, because if you suddenly lose consciousness, you could harm yourself or others. If you experience a seizure, call your doctor immediately or get emergency medical treatment.

Clozapine may cause myocarditis (swelling of the heart muscle that may be dangerous) or cardiomyopathy (enlarged or thickened heart muscle that stops the heart from pumping blood normally). If you experience any of the following symptoms, call your doctor immediately: extreme tiredness; flu like symptoms; difficulty breathing or fast breathing; fever; chest pain; or fast, irregular, or pounding heartbeat.

Clozapine may cause dizziness, lightheadedness, or fainting when you stand up, especially when you first start taking it or when your dose is increased. Tell your doctor if you have or have had a heart attack, heart failure, or a slow, irregular heartbeat or are taking medications for high blood

pressure. Also tell your doctor if you have severe vomiting or diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment. Your doctor will probably start you on a low dose of clozapine and gradually increase your dose to give your body time to adjust to the medication and decrease the chance that you will experience this side effect. Talk to your doctor if you do not take clozapine for 2 days or longer. Your doctor will probably tell you to restart your treatment with a low dose of clozapine.

Use in Older Adults:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as clozapine have an increased chance of death during treatment.

Clozapine is not approved by the Food and Drug Administration (FDA) for the treatment of behavior problems in older adults with dementia. Talk to the doctor who prescribed clozapine if you, a family member, or someone you care for has dementia and is taking this medication. For more information visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

Why is this medication prescribed?

Clozapine is used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions) in people who have not been helped by other medications or who have tried to kill themselves and are likely to try to kill or harm themselves again. Clozapine is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

How should this medicine be used?

Clozapine comes as a tablet, an orally disintegrating tablet (tablet that dissolves quickly in the mouth), and an oral suspension (liquid) to take by mouth. It is usually taken once or twice daily. Take clozapine at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take clozapine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not try to push the orally disintegrating tablet through the foil packaging. Instead, use dry hands to peel back the foil. Immediately take out the tablet and place it on your tongue. The tablet will quickly dissolve and can be swallowed with saliva. No water is needed to swallow disintegrating tablets.

To measure clozapine oral suspension, follow these steps:

1. Make sure the cap is tight on the oral suspension container by turning the cap clockwise (to the right). Shake the bottle up and down for 10 seconds before use.
2. Remove the bottle cap by pushing down on the cap, then turn it counterclockwise (to the left). The first time you open a new bottle, push the adaptor into the bottle until the top of the adaptor is lined

up with the top of the bottle.

3. If your dose is 1 mL or less, use the smaller (1 mL) oral syringe. If your dose is more than 1 mL, use the larger (9 mL) oral syringe.
4. Fill the oral syringe with by air by drawing back the plunger. Then insert the open tip of the oral syringe into the adaptor. Push all the air from the oral syringe into the bottle by pushing down on the plunger.
5. While holding the oral syringe in place, carefully turn the bottle upside down. Draw some of the medication out of the bottle into the oral syringe by pulling back on the plunger. Be careful not to pull the plunger all the way out.
6. You will see a small amount of air near the end of the plunger in the oral syringe. Push on the plunger so the medication goes back into the bottle and the air disappears. Pull back on the plunger to draw your correct medication dose into the oral syringe.
7. While still holding the oral syringe in the bottle, carefully turn the bottle upwards so the syringe is on top. Remove the oral syringe from the bottle neck adaptor without pushing on the plunger. Take the medication right after you draw it into the oral syringe. Do not prepare a dose and store it in the syringe for later use.
8. Place the open tip of the oral syringe into one side of your mouth. Tightly close your lips around the oral syringe and push on the plunger slowly as the liquid goes into your mouth. Swallow the medication slowly as it goes into your mouth.
9. Leave the adaptor in the bottle. Place the cap back on the bottle and turn it clockwise (to the right) to tighten it.
10. Rinse the oral syringe with warm tap water after each use. Fill a cup with water and place the tip of the oral syringe into the water in the cup. Pull back on the plunger and draw the water into the oral syringe. Push on the plunger to squirt the water into a sink or a separate container until the oral syringe is clean. Allow the oral syringe air dry and dispose of any leftover rinse water.

Clozapine controls schizophrenia but does not cure it. It may take several weeks or longer before you feel the full benefit of clozapine. Continue to take clozapine even if you feel well. Do not stop taking clozapine without talking to your doctor. Your doctor will probably want to decrease your dose gradually.

Other uses for this medicine

This medication should not be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking clozapine,

- tell your doctor and pharmacist if you are allergic to clozapine, any other medications, or any of the ingredients in clozapine tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention those listed in the IMPORTANT WARNING section and any of the following: antihistamines such as diphenhydramine (Benadryl); antibiotics such as ciprofloxacin (Cipro) and erythromycin (E.E.S., E-Mycin, others); benztropine (Cogentin); cimetidine (Tagamet); bupropion (Aplenzin, Wellbutrin,

Zyban, in Contrave); cyclobenzaprine (Amrix); escitalopram (Lexapro); medications for anxiety, high blood pressure, mental illness, motion sickness, or nausea; medications for irregular heartbeat such as encainide, flecainide, propafenone (Rythmol), and quinidine (in Nuedexta); oral contraceptives; medications for seizures such as carbamazepine (Equetro, Tegretol, Teril, others) or phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); sedatives; selective serotonin reuptake inhibitors (SSRIs) such as duloxetine (Cymbalta), fluoxetine (Prozac, Sarafem, Selfemra, others), fluvoxamine (Luvox), paroxetine (Brisdelle, Paxil, Pexeva), and sertraline (Zoloft); sleeping pills; terbinafine (Lamisil); and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- in addition to the condition listed in the IMPORTANT WARNING section, tell your doctor if you or anyone in your family has ever had a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death) or diabetes. Tell your doctor if you have constipation, nausea, vomiting, or stomach pain or distension; or if you have or have ever had problems with your urinary system or prostate (a male reproductive gland); dyslipidemia (high cholesterol levels); paralytic ileus (condition in which food cannot move through the intestine); glaucoma; high or low blood pressure; trouble keeping your balance; or heart, kidney, lung, or liver disease. Also tell your doctor if you have ever had to stop taking a medication for mental illness because of severe side effects.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breastfeeding. If you become pregnant while taking clozapine, call your doctor. Clozapine may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking clozapine.
- you should know that alcohol can add to the drowsiness caused by this medication.
- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia, and taking clozapine or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking clozapine: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the orally disintegrating tablets contain aspartame that forms phenylalanine.

What special dietary instructions should I follow?

Talk to your doctor about drinking caffeinated beverages while taking this medicine.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you miss taking clozapine for more than 2 days, you should call your doctor before taking any more medication. Your doctor may want to restart your medication at a lower dose.

What side effects can this medication cause?

Clozapine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- drowsiness
- dizziness, feeling unsteady, or having trouble keeping your balance
- increased salivation
- dry mouth
- restlessness
- headache

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNINGS or SPECIAL PRECAUTIONS sections, call your doctor immediately:

- constipation; nausea; stomach swelling or pain; or vomiting
- shaking hands that you cannot control
- fainting
- falling
- difficulty urinating or loss of bladder control
- confusion
- changes in vision
- shakiness
- severe muscle stiffness
- sweating
- changes in behavior
- unusual bleeding or bruising
- loss of appetite
- upset stomach
- yellowing of the skin or eyes
- pain in upper right part of the stomach

- lack of energy

Clozapine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light and excess heat and moisture (not in the bathroom). Do not refrigerate or freeze the oral suspension.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- dizziness
- fainting
- slow breathing
- change in heartbeat
- loss of consciousness

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to clozapine.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Clozaril[®]
- FazaClo[®] ODT
- Versacloz[®]

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