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Clozapine: Patient drug information

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(For additional information see "Clozapine: Drug information" and see "Clozapine: Pediatric drug information")

Brand Names: US Clozaril; FazaClo; Versacloz

Brand Names: Canada AA-Clozapine; Clozaril; Gen-Clozapine

Warning

- This drug may lower the ability of your bone marrow to make white blood cells. This can lead to very bad and sometimes deadly infections. You will need to have your blood work checked before, during, and after treatment is stopped. Do what the doctor tells you about blood tests while taking this drug.
- This drug may cause seizures in some people. The chance of seizures may be higher with higher doses or if you have ever had seizures. Use care when driving and doing other tasks or actions (like climbing and swimming) that may not be safe for you or others if you pass out.
- This drug may raise the chance of a very bad and sometimes deadly heart problem (myocarditis). Call
 your doctor right away if you have a big weight gain, a heartbeat that does not feel normal, chest pain or
 pressure, fast heartbeat, fever, flu-like signs, shortness of breath, swelling in the arms or legs, or very bad
 dizziness or passing out.
- Low blood pressure, passing out, slow heartbeat, and heart attacks have happened with this drug. These
 problems can be deadly. Do not take more than you were told or raise your dose faster than you were
 told. Tell your doctor if you have heart problems or brain problems. Tell your doctor if you have lots of fluid
 loss or if you take drugs for high blood pressure.
- There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.
- You may only get this drug through a special program. Talk with your doctor.

What is this drug used for?

- It is used to treat schizophrenia.
- It is used to treat problems with how one acts.

• It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- · If you have an allergy to clozapine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have a low white blood cell count.
- If you have bone marrow disease.
- If you have any of these health problems: Low potassium or magnesium levels.
- If you have ever had a low white blood cell count when taking a drug before.
- If you are taking any drugs that can stop your bone marrow from making some of the cells that your body needs. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.
- · If you are not able to get blood tests as you have been told by your doctor.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- High blood sugar or diabetes, high cholesterol, and weight gain have happened with drugs like this one. These changes may raise the chance of heart and brain blood vessel disease. Talk with the doctor.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely. Tell your doctor if you get signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Call your doctor right away if you have any signs of infection like fever, chills, flu-like signs, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or a wound that will not heal.
- An unsafe heartbeat that is not normal (long QT on ECG) has happened with this drug. Chest pain, heart attack, and sudden deaths have also rarely happened in people taking this drug. Talk with the doctor.
- Blood clots have happened with this drug. Tell your doctor if you have ever had a blood clot. Talk with your doctor.

- Talk with your doctor before you drink alcohol or use other drugs and natural products that slow your actions.
- · Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- Dizziness, sleepiness, and feeling less stable may happen with this drug. These may lead to falling. Broken bones or other health problems can happen from falling. Talk with the doctor.
- Very bad and sometimes deadly liver problems have happened with this drug. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia. Talk with your doctor.
- If you are 60 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.

Oral-disintegrating tablet:

• If you have phenylketonuria (PKU), talk with your doctor. Some products have phenylalanine.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high or low blood pressure like very bad headache or dizziness, passing out, change in eyesight.
- Shakiness, trouble moving around, or stiffness.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Swelling, warmth, numbness, change of color, or pain in a leg or arm.
- · Coughing up blood.
- Blue or very pale skin in the arms or legs.
- Seizures.
- Feeling very tired or weak.
- Slow heartbeat.
- · Very bad constipation.
- · Change in eyesight.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.

• Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. This muscle problem may not go away even if this drug is stopped. Sometimes, signs may lessen or go away over time after this drug is stopped. The risk of tardive dyskinesia may be greater in people with diabetes and in older adults, especially older women. The risk is also greater the longer you take this drug or with higher doses. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Feeling sleepy.
- · Constipation.
- Dry mouth.
- Upset stomach or throwing up.
- Weight gain.
- Not able to sleep.
- Drooling.
- · Headache.
- · Sweating a lot.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with or without food.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- You will need to have heart function tests while taking this drug. Talk with the doctor.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- If you start or stop smoking, talk with your doctor. How much drug you take may need to be changed.
- Tell your doctor if you use caffeine products (for example, tea, coffee, cola) and chocolate. How much of this drug you take may need to be changed.

• This drug can cause very bad stomach or bowel problems like very bad constipation or bowel block. Sometimes, this has been deadly. To help avoid these problems, drink lots of noncaffeine liquids unless told to drink less liquid by your doctor. Laxatives may also help. Talk with your doctor.

Oral-disintegrating tablet:

• Do not push the tablet out of the foil when opening. Use dry hands to take it from the foil. Place on your tongue and let it melt. Water is not needed. Do not swallow it whole. You may chew the tablet.

Liquid (suspension):

- · Shake well before use.
- Measure liquid doses carefully. Use the measuring device that comes with this drug.
- Do not draw into a syringe and store for future use.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you miss 2 or more days of this drug, call your doctor to find out how to restart.

How do I store and/or throw out this drug?

All products:

- Store at room temperature. Do not refrigerate or freeze.
- Store in a dry place. Do not store in a bathroom.
- Protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Oral-disintegrating tablet:

- Store in pouch until ready for use.
- Use oral-disintegrating tablet right after opening. Throw away any part of opened pouch that is not used.
 <u>Liquid (suspension):</u>
- Throw away any part not used 100 days after opening the first time.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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