

# Getting started on **AA-CLOZAPINE**

What you need to know

Pr  Clozapine  
(CLOZAPINE)

 pharma

## “My doctor prescribed AA-CLOZAPINE. Why, and what’s next?”

Your doctor prescribed AA-CLOZAPINE because you’ve tried at least two other medications for schizophrenia and they haven’t worked for you. This is called “treatment-resistant schizophrenia” and means that your symptoms did not improve, or that you had too many side effects.

That happens to more people with schizophrenia than you may think, and there are treatments specifically for this type of schizophrenia. There are also many things that you can do to look after your own well-being during the treatment journey, like eating well and exercising, to help support your medical treatment.

There are some important things you need to know before starting treatment with AA-CLOZAPINE. And that’s where this booklet can help. It will talk about:

- Why you’ll need regular blood tests, and when you’ll need to take them
- How to take AA-CLOZAPINE
- Common and uncommon side effects
- Other drugs that interact with AA-CLOZAPINE
- Where you can find more information and support



## “What should I expect from AA-CLOZAPINE?”

AA-CLOZAPINE helps manage symptoms of schizophrenia. In clinical studies, AA-CLOZAPINE has shown to improve both positive symptoms, like hallucinations and delusions, and negative symptoms, such as emotional flatness and a lack of feeling pleasure or interest in life.

**Before you start treatment, your doctor will:**

- ✓ Check your body weight
- ✓ Take blood tests to check your blood sugar levels

Your doctor will continue to monitor your weight and blood sugar levels for as long as you are being treated. You will also need to have regular blood tests to check your white blood cell counts (please see next page).

***Treatment-resistant schizophrenia is more common than you think.***

*For at least 50% of schizophrenia patients, conventional antipsychotic treatments don’t completely work.*

≥20%	treatment doesn’t work on patients with positive-symptoms
30%	treatment works only partially



## “Why do I need regular blood tests? And how does this work?”

Once you start treatment with AA-CLOZAPINE, you will need to have regular blood tests. These tests are needed because a very rare condition called agranulocytosis can occur when taking AA-CLOZAPINE. It causes the number of white blood cells to drop and makes it difficult for the body to fight infection.

Agranulocytosis is rare—it happens in about 0.7% of cases. Regular blood tests help prevent or reverse this condition because they allow your doctor to spot changes early on, before you start having symptoms.

Your doctor will enroll you in the AA-CLOZAPINE Risk Management Program and Patient Registry that has been set up for your doctor, lab, and pharmacist to connect easily and to work together to ensure you get your medication only when it's safe.

### Benefits of regular check-ups:



- Your progress can be monitored
- Regular contact with a healthcare team
- It's a chance to ask questions & discuss concerns
- Your healthcare team can monitor & help manage side effects

*Contact your doctor immediately at the first signs of a cold, flu-like symptoms, fever, sore throat, or any other signs of infection, as well as weakness or a general feeling of unwellness. Your doctor may check your blood cell count.*

## You will need to go for blood tests:

- **before** starting AA-CLOZAPINE,
- **every week** for the first 26 weeks of treatment,
- then, **every two weeks** for the next 26 weeks of treatment, and
- after a year of therapy, at least **monthly** for the duration of therapy.

**Important note:** You must have regular blood tests done in order to continue treatment on AA-CLOZAPINE. Your doctor and pharmacist will be notified if the results trigger a yellow, flashing yellow, red, or critical alert.

## Blood test results will be closely monitored:\*

GREEN STATUS	YELLOW/FLASHING YELLOW ALERT	RED ALERT	CRITICAL ALERT
<p><b>Normal level of white blood cells</b></p> <ul style="list-style-type: none"> <li>• You will continue treatment</li> </ul>	<p><b>At the lower end of the normal range for white blood cells</b></p> <ul style="list-style-type: none"> <li>• You will continue treatment, but you may need more frequent blood tests</li> </ul>	<p><b>Low number of white blood cells</b></p> <ul style="list-style-type: none"> <li>• Your doctor will want to monitor you</li> <li>• You will go for a repeat blood test</li> <li>• Your doctor will stop treatment if the low number is confirmed</li> </ul>	<p><b>The number of white blood cells continues to drop</b></p> <ul style="list-style-type: none"> <li>• You will be placed in protective isolation and will be closely monitored for signs of infection by your doctor</li> </ul>

\* Pharmacists, nurses, coordinators, and doctors have access to the AA-CLOZAPINE Risk Management Program where they can actively monitor the results.

## “How do I take AA-CLOZAPINE?”

Your doctor will decide your dosage of AA-CLOZAPINE. Usually, treatment starts with one half of a 25 mg tablet once or twice on the first day. Your doctor will then gradually increase your dose until the ideal dose for you is reached—usually between 300 and 450 mg per day. Some people need higher doses, up to a maximum of 900 mg per day.

Your prescription will be filled for one, two, or four weeks at a time.

Your pharmacist can only dispense AA-CLOZAPINE if the required blood test has been done. Your blood test results will be sent to your pharmacist so he or she knows that you can receive your refill of AA-CLOZAPINE.

*Do not stop taking AA-CLOZAPINE without talking to your doctor. Stopping AA-CLOZAPINE can cause unwanted side effects.*



### Do NOT take AA-CLOZAPINE if you:

- Are allergic (hypersensitive) to clozapine or any of the other ingredients listed in “What the non-medicinal ingredients are”
- Are unable to have regular blood tests
- Have ever been diagnosed as having a low number of white blood cells (except if this was following a treatment for cancer)
- Suffer or have ever suffered from bone marrow disease or disease affecting blood cell formation
- Have liver, kidney, or heart problems (e.g., myocarditis, cardiomyopathy, heart failure)
- Suffer from uncontrolled seizures
- Have problems with alcohol or drug abuse
- Suffer or have ever suffered from severe constipation, obstruction of the bowel, or any other condition which has affected your large bowel

If you think you are allergic to AA-CLOZAPINE, ask your doctor for advice before taking AA-CLOZAPINE.

## When to take AA-CLOZAPINE

Try to take AA-CLOZAPINE at the same time each day. This will help you remember when to take your medicine.

## If you miss a dose of AA-CLOZAPINE...

You can take the missed dose if you remember within 2 hours of your normal dosing schedule. If not, skip the missed dose and continue with your regular dosing schedule. **Do not** take a double dose to make up for the missed dose. If you’ve forgotten to take AA-CLOZAPINE for more than 2 days, talk to your doctor before taking any more medication. Your doctor may want to restart your treatment at a lower dose.

## If you move or go on vacation...

If you are planning to move or go on vacation, it is important to inform your doctor immediately (at least 2 to 3 weeks in advance). Your doctor can then help make arrangements for you to get your medication and regular blood tests wherever you decide to go.



*For treatment to be successful, you must follow your doctor’s dosage instructions exactly. Under no circumstances should you take more or less than the prescribed dose. If you think the dosage is too weak or too strong, talk to your doctor.*

## “What are the side effects of AA-CLOZAPINE?”

The most common side effects are drowsiness, dizziness, a rapid heartbeat, constipation, and increased production of saliva. Other possible side effects include weight gain and urinary retention (less frequent urination).

AA-CLOZAPINE may lower your blood pressure, especially at the start of treatment. This may result in light-headedness or fainting.

### Tips to help you manage side effects

Side effect	Suggestions
Drowsiness	<ul style="list-style-type: none"> <li>• Avoid activities where you need to be alert (e.g., driving, using machines, swimming, climbing)</li> </ul>
Constipation	<ul style="list-style-type: none"> <li>• Include high-fibre foods in your diet (e.g., beans, fruits, vegetables, bran, whole-grain cereals)*</li> <li>• Drink lots of water</li> <li>• Stay physically active†</li> <li>• Speak to your doctor or pharmacist if these tips don't help</li> </ul>
Increased saliva production/drooling	<ul style="list-style-type: none"> <li>• Try placing a towel over your pillow to help keep it clean</li> <li>• Chew gum or suck on an ice cube</li> </ul>
Weight gain	<ul style="list-style-type: none"> <li>• Speak to a dietitian about making dietary changes to help control your weight</li> <li>• Try to choose healthy foods (fruits, vegetables, whole grains) and avoid too much sugar or processed food (e.g., fries, chips, donuts)</li> <li>• Try to be more physically active (e.g., go for more walks)†</li> </ul>

\* Speak to your doctor or a registered dietitian before making changes to your diet.

† Speak to your doctor before making changes to your exercise routine.

*It is important to keep your doctor informed about any side effects you have while taking AA-CLOZAPINE.*

## “Do any of my medications interact with AA-CLOZAPINE?”

Some medications or drugs can interfere with AA-CLOZAPINE and cause unwanted side effects. It is important to know them so that you can talk to your doctor if needed.

- AA-CLOZAPINE may intensify the effect of alcohol, sleeping pills, and tranquilizers.
- AA-CLOZAPINE may also increase the effect of anti-allergy (antihistamine) medications.

• Other medicines may interfere with the effectiveness of AA-CLOZAPINE. They include: certain antibiotics, medicines used to treat depression, convulsions, or ulcers of the stomach, certain drugs effective against fungal or viral infections, and birth control pills.

### Let your doctor know about all medications and substances you are taking—some of them may affect how AA-CLOZAPINE works.

Inform your doctor before taking any other medications, including:

- Carbamazepine
- Phenytoin
- Omeprazole
- Rifampicin
- Erythromycin
- Cimetidine
- Valproic acid
- Antifungals (fluconazole, miconazole, clotrimazole, etc.)
- SSRI antidepressants (fluvoxamine, paroxetine, sertraline, fluoxetine, citalopram)
- Ciprofloxacin
- Caffeine
- Tobacco smoke
- Narcotics
- Benzodiazepines
- Norepinephrine
- Epinephrine
- MAO (monoamine oxidase) inhibitors
- Any drugs for bone marrow suppression



## “What else can I do to help manage my condition?”

### Staying healthy—body and mind

Living with schizophrenia can take a toll on both your body and mind. Many of the antipsychotic drugs used to treat schizophrenia can cause side effects such as drowsiness or weight gain.

That’s why it’s especially important to try and maintain a healthy lifestyle in order to get the full benefits of the medication and avoid or reduce side effects. Although it may be challenging, it is important to try to:

- ✔ Exercise
- ✔ Make healthy food choices
- ✔ Avoid caffeine, sugars, and processed foods
- ✔ Avoid smoking, alcohol, and other drugs\*
- ✔ Keep records and monitor any changes in health (i.e., weight, mood, new medication)

It might also help you to seek support from a counselor or social worker to address specific challenges you are facing in this area.

\* It is important that you speak to your healthcare team before you start or quit smoking. Abrupt changes in smoking habits may change the effect of AA-CLOZAPINE and may lead to side effects.



## “What is the AA-CLOZAPINE Risk Management Program?”

The AA-CLOZAPINE Risk Management Program is run by the company that makes AA-CLOZAPINE. It helps coordinate the blood tests you need to have done while you’re on AA-CLOZAPINE.

The program helps facilitate communication between your doctor, pharmacist, and the blood testing laboratory to ensure you’re getting appropriate care, and that the risk of serious blood issues is managed.

Once your blood test is completed, the AA-CLOZAPINE Risk Management Program ensures that your doctor and pharmacist receive the results of your blood test. This helps to detect problems early on so that any issues can be managed.

## “Why does my doctor need my information?”

### Why your doctor needs your consent

Clozapine is produced by several different suppliers. Each supplier has a different monitoring system (e.g., the AA-CLOZAPINE Risk Management Program) to ensure patient safety. Should your doctor and/or pharmacist (with the approval of your doctor) change the brand of clozapine you are taking, you will be transferred to a different monitoring system. If this happens, it's very important that your new supplier is able to access your past blood test results in order to help your doctor ensure that you are properly monitored.

It's also important to check with all registries at the start of the treatment that you haven't experienced a decrease of your white blood cell count with clozapine in the past. Your consent is needed to allow this verification and sharing of information to take place.

*Your personal information will ONLY be used to ensure that you are properly monitored while using any brand of clozapine. It will not be used for other purposes.*

### Why your doctor asks for your personal information

Information such as your initials, birth date, gender, and health card number is collected and used for several reasons. Since this information is specific to you, it helps to ensure that your test results are not mixed up with those of another person on the same medication. Using this information also avoids the need to use your full name and therefore protects your privacy.



## “What else do I need to know?”

BEFORE you use AA-CLOZAPINE, be sure to tell your doctor or pharmacist if you:

- Suffer from enlargement of the prostate
- Have a history of seizures (e.g. epilepsy)
- Have glaucoma (an eye condition)
- Suffer from diabetes
- Have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reasons, or take oral contraceptives (“the Pill”)
- Have a history of bone marrow disorder
- Have a paralytic ileus or other serious gastrointestinal problems
- Suffer from constipation
- Have or have had heart problems
- Have heart disease or family history of abnormal conduction in the heart called “prolongation of the QT interval”
- Have had a stroke
- Have or have had lung disease
- Have Alzheimer's disease
- Suffer from a condition called dementia
- Are pregnant or planning to become pregnant
- Are breast-feeding



## Warnings and precautions

Clozapine has been associated with an increased rate of death when used in elderly patients with dementia and thus is not indicated in this group of patients.

AA-CLOZAPINE may cause a potentially life-threatening decrease in your white blood cell count (agranulocytosis or granulocytopenia) and should not be used if you have a history of bone marrow disorder. While taking AA-CLOZAPINE, your doctor will enroll you in a patient registry program where you will be required to undergo regular blood tests.

AA-CLOZAPINE has been associated with potentially serious heart problems (e.g. myocarditis, pericarditis, pericardial effusion, or cardiomyopathy) and should not be used if you have a history of heart disease.

## Pregnancy and breast-feeding

AA-CLOZAPINE should only be taken during pregnancy if your doctor specifically prescribes it. Therefore, you should consult your doctor if you are, or plan on becoming, pregnant.

Since AA-CLOZAPINE can pass into breast milk, mothers taking AA-CLOZAPINE should not breast-feed.

## Other serious side effects you should know about

Serious side effects, how often they happen, and what to do about them				
Symptom/Effect	Talk to your healthcare professional		Stop taking AA-CLOZAPINE and get immediate medical help	
	Only if severe	In all cases		
Very common	New or worsening constipation		☑	
Common	<b>Low blood pressure:</b> Weakness, dizziness, fainting		☑	
	High level of a specific type of white blood cells, increased white blood cell count		☑	
	Sudden weakness or numbness of the face, arms, or legs, and speech or vision problems			☑
	Rigid/stiff muscles, high fever, rapid or irregular heartbeat, sweating, state of confusion, or reduced consciousness			☑
	<b>Seizures:</b> Loss of consciousness with uncontrollable shaking			☑
Uncommon	<b>Signs of infection:</b> Fever, severe chills, sore throat, or mouth ulcers (sign of reduced number of white cells in your blood, leading to a higher sensitivity to infection)		☑	

*This is not a complete list of side effects. For any unexpected side effects while taking AA-CLOZAPINE, please contact your doctor or pharmacist.*

Serious side effects, how often they happen, and what to do about them				
Symptom/Effect		Talk to your healthcare professional		Stop taking AA-CLOZAPINE and get immediate medical help
		Only if severe	In all cases	
Rare	<b>Blood clots:</b> Swelling, pain, and redness in an arm or leg that can be warm to the touch. You may develop sudden chest pain, difficulty breathing, and heart palpitations		✓	
	Chest pain due to inflammation of the heart muscle or the outer lining of the heart		✓	
	Food getting into the lung		✓	
	Abdominal pain due to inflammation of the pancreas		✓	
	Low level of red blood cells		✓	
	<b>Liver disorder:*</b> Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite	✓		
	<b>Signs of respiratory tract infection or pneumonia:</b> Fever, coughing, difficulty breathing, or wheezing		✓	
	<b>Diabetes (signs of high sugar levels in the blood):</b> Excessive thirst, dry mouth, and passing large amounts of urine		✓	

\* You should not take AA-CLOZAPINE if you have active liver disease. Please contact your doctor if you experience yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, or loss of appetite.

Serious side effects, how often they happen, and what to do about them				
Symptom/Effect		Talk to your healthcare professional		Stop taking AA-CLOZAPINE and get immediate medical help
		Only if severe	In all cases	
Very rare	Chest pain, difficulty breathing, or other respiratory symptoms			✓
	Fast and irregular heartbeat that persists when you are at rest, possibly accompanied by shortness of breath and swelling of the feet or legs		✓	
	<b>Thrombocytopenia (signs of low level of blood platelets):</b> Spontaneous bleeding or bruising		✓	
	<b>High platelet levels in the blood</b>	✓		
	Impaired orientation/confusion, nausea/vomiting, excessive urination, abdominal pain with high blood sugar		✓	
	Feeling sick, vomiting with severe/prolonged constipation		✓	
	<b>Allergic reaction:</b> Swelling mainly of the face, mouth, and throat as well as, the tongue, which may be itchy or painful; difficulty in breathing			✓
	Inflammation of the kidney		✓	
	Long-lasting (more than 4 hours of duration) and painful erection of the penis			✓



# What you need to know about AA-CLOZAPINE at a glance

- ✔ Take your medication exactly as your doctor prescribed.
- ✔ You will need to have regular blood tests while on AA-CLOZAPINE.
- ✔ Do NOT stop taking AA-CLOZAPINE without talking to your doctor.
- ✔ Tell your doctor about all medications and substances you are taking—even non-prescription ones.
- ✔ Contact your doctor immediately if you have signs of an infection (e.g., fever, sore throat, weakness).

*If you have questions about your treatment journey ahead, talk to your healthcare team. They are here to help and support you!*

- *To learn more, you can also go to our website: **[www.aaclozapine.ca](http://www.aaclozapine.ca)**.*

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