

FOR CAREGIVERS

“My loved one
was prescribed
AA-CLOZAPINE.
What’s next?”

What you need to know about AA-CLOZAPINE
and your role as a caregiver

Pr  Clozapine
(CLOZAPINE)

 pharma

About this booklet

You may or may not realize it, but as a loved one of someone with schizophrenia, you play a crucial role in their mental well-being. You have the ability to recognize the warning signs of a possible relapse, to help them stay on track with treatment, and most importantly, to help them feel connected and supported.

Now that your loved one has been prescribed AA-CLOZAPINE, you can also help ensure that they go for regular blood tests—a necessary part of treatment. AA-CLOZAPINE carries a small but significant risk of certain blood issues, and your loved one will need to have regular blood tests in order to continue treatment with AA-CLOZAPINE.

This booklet will help provide you with what you need to know about AA-CLOZAPINE: why it was prescribed, what to expect, side effects, and what some of the risks of treatment are. But it will also provide important information to help support you as a caregiver, such as how to recognize the signs of a relapse, and where to get help if you need it.

Of course, if you still have questions, feel free to talk to your loved one's doctor, or to contact some of the support resources at the back of this booklet. There is support out there for you too!



As a loved one of someone with schizophrenia, you can:

- ✓ Help your loved one feel supported and connected
- ✓ Help your loved one stay on track with treatment
- ✓ Recognize the signs of a relapse
- ✓ Keep important records (e.g. of medications, side effects, schizophrenia symptoms)

“Why was my loved one prescribed AA-CLOZAPINE?”

AA-CLOZAPINE is for something called “treatment-resistant schizophrenia”. Schizophrenia is considered “treatment-resistant” if someone has tried at least two schizophrenia medications and they haven't worked, either because their symptoms didn't improve, or because they had too many side effects.

AA-CLOZAPINE helps manage symptoms of schizophrenia. Research has shown that clozapine helps 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.

Once your loved one starts treatment with AA-CLOZAPINE, they will be enrolled in the AA-CLOZAPINE Risk Management Program and Patient Registry. This program will allow them

to be closely monitored by a team of professionals and ensure they only get medication when it's safe to do so. Getting regular check-ups also gives your loved one a chance to ask questions and discuss any concerns they may have with their healthcare team.

Your loved one will need regular blood tests while on treatment with AA-CLOZAPINE. You can play a role in helping ensure they go for regular testing.



“Why does my loved one need regular blood tests? How does this work?”

Once your loved one starts treatment with AA-CLOZAPINE, they must go for 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 the doctor to spot changes early on, before symptoms start.

The doctor will enroll your loved one in the AA-CLOZAPINE Risk Management Program and Patient Registry. This program has been set up for your loved one’s doctor, lab, and pharmacist to connect easily and to work together to ensure your loved one only gets medication when it’s safe to do so.



Watch for the signs of an infection in your loved one. They could indicate a blood problem:

- ✔ The first signs of a cold
- ✔ Flu-like symptoms
- ✔ Fever
- ✔ Sore throat
- ✔ Weakness
- ✔ General feeling of unwellness
- ✔ Any other signs of infection

If you notice any of these signs, contact your loved one’s doctor right away.

Blood testing frequency

Your loved one 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:** Your loved one must have regular blood tests done in order to continue treatment on AA-CLOZAPINE. Your loved one’s 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>Normal level of white blood cells</p> <ul style="list-style-type: none"> • Treatment can be continued 	<p>At the lower end of the normal range for white blood cells</p> <ul style="list-style-type: none"> • Treatment can continue, but more frequent blood tests may be needed 	<p>Low number of white blood cells</p> <ul style="list-style-type: none"> • Your loved one’s doctor will want to monitor them • Your loved one will go for a repeat blood test • Your loved one’s doctor will stop treatment if the low number is confirmed 	<p>The number of white blood cells continues to drop</p> <ul style="list-style-type: none"> • Your loved one will be placed in protective isolation and will be closely monitored for signs of infection by their doctor

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

“How is AA-CLOZAPINE taken?”

AA-CLOZAPINE is given as a tablet taken by mouth, and it should be taken at the same time each day.

Your loved one’s doctor will decide the dosage of AA-CLOZAPINE. Usually, treatment starts with one half of a 25 mg tablet once or twice on the first day. The dose will then gradually be increased until the ideal dose is reached—

Example of a dosing schedule

Below is an example of an AA-CLOZAPINE dosing regimen. It shows how the dosage is gradually increased.

WEEK 1	Morning dose	Evening dose	Total daily dose	WEEK 2	Morning dose	Evening dose	Total daily dose
Day 1	12.5 mg	12.5 mg (optional)	12.5–25 mg	Day 8	75 mg	100 mg	175 mg
Day 2	25 mg	—	25 mg	Day 9	100 mg	100 mg	200 mg
Day 3	25 mg	25 mg	50 mg	Day 10	100 mg	125 mg	225 mg
Day 4	25 mg	50 mg	75 mg	Day 11	100 mg	150 mg	250 mg
Day 5	50 mg	50 mg	100 mg	Day 12	125 mg	150 mg	275 mg
Day 6	50 mg	75 mg	125 mg	Day 13	150 mg	150 mg	300 mg
Day 7	50 mg	100 mg	150 mg	Day 14	150 mg	150 mg	300 mg

usually between 300 and 450 mg per day. Some people need higher doses, up to a maximum of 900 mg per day.

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



Your loved one must take AA-CLOZAPINE exactly as their doctor has prescribed. They should not stop taking AA-CLOZAPINE without talking to their doctor. Stopping AA-CLOZAPINE suddenly can cause unwanted side effects.

If your loved one misses a dose of AA-CLOZAPINE...

Your loved one can take the missed dose as long as it’s within 2 hours of the normal dosing schedule. If not, skip the missed dose and continue with the regular dosing schedule. Your loved one **MUST NOT take a double dose to make up for the missed dose.**

If your loved one has forgotten to take AA-CLOZAPINE for more than 2 days, they should talk to their doctor before taking any more medication. The doctor may want to restart treatment at a lower dose.

If your loved one moves or goes on vacation...

If your loved one is planning to move or go on vacation, it is important the doctor is informed immediately (at least 2 to 3 weeks in advance). The doctor can then help make arrangements for your loved one to get medication and regular blood tests wherever they decide to go.

“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 blood pressure, especially at the start of treatment. This may result in light-headedness or fainting.

Your loved one’s doctor should be informed about any side effects that may occur during treatment with AA-CLOZAPINE.

Tips to help your loved one manage side effects

Side effect	Suggestions
Drowsiness	<ul style="list-style-type: none"> • Avoidance of activities that require alertness (e.g., driving, using machines, swimming, climbing)
Constipation	<ul style="list-style-type: none"> • Eating more high-fibre foods (e.g. beans, fruits, vegetables, bran, whole-grain cereals)* • Drinking lots of water • Staying physically active†
Increased saliva production/drooling	<ul style="list-style-type: none"> • Try placing a towel over your loved one’s pillow to help keep it clean • Chewing gum or sucking on an ice cube
Weight gain	<ul style="list-style-type: none"> • Choosing healthy foods (fruits, vegetables, whole grains) and avoiding too much sugar or processed food (e.g. fries, chips, donuts) • Being more physically active (e.g. going for more walks)† • Consulting a dietitian about making dietary changes to help control weight

* You or your loved one should speak to their doctor or a registered dietitian before making dietary changes.

† You or your loved one should speak to their doctor before making changes to an exercise routine.

“Do any medications interact with AA-CLOZAPINE?”

Some medications or drugs can interfere with AA-CLOZAPINE and cause unwanted side effects.

- 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.

Your loved one’s doctor should know about all medications and substances your loved one is taking—some of them may affect how AA-CLOZAPINE works.

Your loved one’s doctor should know about any medications and substances, 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

* It is important to consult your loved one’s healthcare team if your loved one starts or quits smoking. Abrupt changes in their smoking habits during treatment 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 your loved one needs to have done while on AA-CLOZAPINE.

The program helps facilitate communication between your loved one’s doctor, pharmacist, and the blood testing laboratory to ensure that the risk of serious blood issues is managed.

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

Benefits of regular check-ups:

- ✓ Your loved one’s progress can be monitored
- ✓ Regular contact with a healthcare team
- ✓ It’s a chance to ask questions and discuss concerns
- ✓ Your loved one’s healthcare team can monitor and help manage side effects

Your loved one will be enrolled in the AA-CLOZAPINE Risk Management Program and Patient Registry, which helps ensure they will be monitored properly while on treatment.

BEFORE your loved one starts treatment with AA-CLOZAPINE, their doctor or pharmacist should know if they:

- 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
- 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 their large bowel
- 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

“What else do I need to know about AA-CLOZAPINE?”

Your loved one should NOT take AA-CLOZAPINE if they:

- Are allergic (hypersensitive) to clozapine or any of the other ingredients in AA-CLOZAPINE
- 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 their large bowel

If you think your loved one is allergic to AA-CLOZAPINE, ask their doctor for advice before your loved one starts taking AA-CLOZAPINE.

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 white blood cell count (agranulocytosis or granulocytopenia) and should not be used if your loved one has a history of bone marrow disorder. While taking AA-CLOZAPINE, your loved one's doctor will enroll them in a patient registry program where they 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 your loved one has a history of heart disease.

Pregnancy and breast-feeding

AA-CLOZAPINE should only be taken during pregnancy if the doctor specifically prescribes it. Therefore, your doctor should be aware if your loved one is pregnant or plans on becoming pregnant.

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

Other serious side effects

Serious side effects, how often they happen, and what to do about them				
Symptom/Effect	Talk to your loved one's healthcare professional		Tell your loved one to stop taking AA-CLOZAPINE and get immediate medical help	
	Only if severe	In all cases		
Very common	New or worsening constipation		✓	
Common	Low blood pressure: 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			✓
	Seizures: Loss of consciousness with uncontrollable shaking			✓
Uncommon	Signs of infection: 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. If your loved one experiences unexpected side effects while taking AA-CLOZAPINE, please contact their doctor or pharmacist.

Serious side effects, how often they happen, and what to do about them

Symptom/Effect	Talk to your loved one's healthcare professional		Tell your loved one to stop taking AA-CLOZAPINE and get immediate medical help	
	Only if severe	In all cases		
Rare	Blood clots: Swelling, pain, and redness in an arm or leg that can be warm to the touch. They 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 lungs		✓	
	Abdominal pain due to inflammation of the pancreas		✓	
	Low level of red blood cells		✓	
	Liver disorder:* Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite	✓		
	Signs of respiratory tract infection or pneumonia: Fever, coughing, difficulty breathing, or wheezing		✓	
	Diabetes (signs of high sugar levels in the blood): Excessive thirst, dry mouth, and passing large amounts of urine		✓	

* Your loved one should not take AA-CLOZAPINE if they have active liver disease. Please contact their doctor if they 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 loved one's healthcare professional		Tell your loved one to 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 they are at rest, possibly accompanied by shortness of breath and swelling of the feet or legs		✓	
	Thrombocytopenia (signs of low level of blood platelets): Spontaneous bleeding or bruising		✓	
	High platelet levels in the blood	✓		
	Impaired orientation/confusion, nausea/vomiting, excessive urination, abdominal pain with high blood sugar		✓	
	Feeling sick, vomiting with severe/prolonged constipation		✓	
	Allergic reaction: 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			✓

Recognizing the signs of a relapse

As a loved one of someone with schizophrenia, you play an important role in helping to spot signs of a possible relapse early on. This is important information for your loved one's doctor since it can signal potential issues, like lack of compliance with medication, or that a medication may not be working.

Staying on track with treatment is the single most important thing your loved one can do to minimize the risk of a relapse. That being said, you can support your loved one by helping make sure they take their medication as prescribed.

Warning signs of a relapse:

- Sleep problems
- Feeling tense, afraid, or unsettled
- Having trouble concentrating
- Feeling irritable or quick-tempered
- Difficulty coping or managing everyday tasks
- Feeling tired or lacking energy
- Feeling depressed or low
- Feeling confused

Helpful tip: Try keeping a diary of important information, like when medication was taken and how much, and possible signs of a relapse (if any). Share the diary with your loved one's doctor so they can get a better sense of how your loved one is doing.



Caring for yourself

When you're in a caregiving role to someone with schizophrenia, it's easy to become absorbed with the needs of the person you are caring for to the point of neglecting your own. It's crucial for you to look after yourself too. After all, taking care of your own needs helps you be a better caregiver to your loved one. Read on for some helpful tips on self-care.

Know your limits.

Say "no" to responsibilities or activities you feel you just can't take on. And don't be afraid to ask for help when you need it. For example, ask a friend or family member to help you out with running errands.

Watch for signs of stress.

These include things like trouble sleeping, headaches, feeling irritable, and withdrawing from friends and family. If you notice any of these signs, take it as a cue to carve out some time for yourself.

Take time for you.

Being a caregiver or companion to someone with schizophrenia can feel overwhelming. So don't feel guilty about carving out some time just for you. Do an activity that *you* enjoy, whether it's going out with friends, reading, or gardening.

Consider a support group.

Sometimes, it can be helpful to speak with other caregivers who share your experiences. Knowing that someone can relate to what you're going through might actually help reduce your stress. Check your local schizophrenia association to see what services they offer.

Be sure to take good care of yourself too. Maintaining your health—body and mind—ultimately benefits your loved one as well.

Where to look for help

There's no question that being a friend or family member of someone with schizophrenia can be stressful. And as much as you want to be there for your loved one, it's important that you look after yourself too. The good news is there's lots of support out there, whether you're simply looking for information or want to connect with a support group.

Other organizations

Schizophrenia Society of Canada

www.schizophrenia.ca
1-800-263-5545
info@schizophrenia.ca

Canadian Psychiatric Association

www.cpa-apc.org
1-800-267-1555
cpa@cpa-apc.org

Centre for Addiction and Mental Health

www.camh.ca
1-800-463-6273
info@camh.ca

Canadian Mental Health Association

www.cmha.ca
1-613-745-7750
info@cmha.ca

Provincial organizations

ALBERTA

Schizophrenia Society of Alberta

www.schizophrenia.ab.ca
1-403-986-9440
info@schizophrenia.ca

BRITISH COLUMBIA

British Columbia Schizophrenia Society

www.bcscs.org
1-888-888-0029
prov@bcscs.org

MANITOBA

Manitoba Schizophrenia Society

www.mss.mb.ca
1-204-786-1616
info@mss.mb.ca

NEW BRUNSWICK

Schizophrenia Society of New Brunswick

www.schizophreniasociety.nb.ca
1-877-240-4412
ssnbmiramichi@nb.aibn.com

NEWFOUNDLAND & LABRADOR

Schizophrenia Society of Newfoundland & Labrador

www.ssnl.org
1-709-777-3335
info@ssnl.org

NOVA SCOTIA

Schizophrenia Society of Nova Scotia

www.ssns.ca
1-902-465-2601
contact@ssns.ca

ONTARIO

Schizophrenia Society of Ontario

www.schizophrenia.on.ca
1-800-449-6367

PRINCE EDWARD ISLAND

Schizophrenia Society of Prince Edward Island

1-902-368-5850
schizophreniapei@pei.aibn.com

QUEBEC

Société Québécoise de la Schizophrénie (SQS)

http://www.schizophrenie.qc.ca
1-514-251-4125
info@schizophrenie.qc.ca

SASKATCHEWAN

Schizophrenia Society of Saskatchewan

http://www.schizophrenia.sk.ca
1-306-584-2620
sssprov@sasktel.net

Important contacts

Write down the names and contact information for the people below.

Physician Name: _____

Phone number: _____

Email address: _____

Pharmacist Name: _____

Phone number: _____

Email address: _____

Nursing unit Name: _____

Phone number: _____

Email address: _____

Social worker Name: _____

Phone number: _____

Email address: _____

Other Name: _____

Phone number: _____

Email address: _____

What you need to know at a glance

About AA-CLOZAPINE...

- ✓ AA-CLOZAPINE needs to be taken exactly as the doctor prescribed.
- ✓ Treatment with AA-CLOZAPINE carries a risk of certain blood issues; your loved one must have regular blood tests for this reason (see page 3 for more information).
- ✓ Your loved one's doctor needs to know about ALL medications and substances your loved one is taking—some of them affect how AA-CLOZAPINE works.
- ✓ Any signs of infection should be reported to your loved one's doctor right away (e.g. fever, sore throat, weakness).
- ✓ For information on what to do about more serious side effects, please see pages 12–14 of this booklet.

About what you can do as a caregiver...

- ✓ Try to help your loved one stay on track with medication—it is the single most important way to help reduce the risk of a relapse.
- ✓ Keep an eye out for warning signs of a relapse (see page 15 of this brochure for more information).
- ✓ Keep a diary of information on your loved one and share it with your loved one's doctor (e.g. when they've taken their medication, how much, side effects, and possible warning signs of a relapse).

If you still have questions about AA-CLOZAPINE or your loved one's condition, please don't hesitate to contact your loved one's doctor. They are there to help.

- *To learn more, you can also go to our website www.aaclozapine.ca.*

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(CLOZAPINE)

 **pharma**