

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrVENCLEXTA®

venetoclax tablets

This Patient Medication Information is written for the person who will be taking **VENCLEXTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **VENCLEXTA**, talk to a healthcare professional.

Serious warnings and precautions box

VENCLEXTA should only be prescribed by a healthcare professional who is experienced in the use of anti-cancer drugs.

The Starting Pack is meant for patients with Chronic Lymphocytic Leukemia (CLL) or Mantle Cell Lymphoma (MCL).

VENCLEXTA can cause the following 2 serious side effects:

- Tumour lysis syndrome (TLS).

To reduce your risk of TLS:

- You will start taking VENCLEXTA at a low dose. Your dose will be increased slowly up to the full dose:
 - Each week for 5 weeks, if you are taking VENCLEXTA for your CLL or MCL.
 - Each day for 3 days, if you are taking VENCLEXTA with azacitidine for your Acute Myeloid Leukemia (AML).
 - Each day for 4 days, if you are taking VENCLEXTA with low-dose cytarabine for your AML.
- If you have CLL or MCL, your doctor will do blood tests during the first 5 weeks to check for TLS.
- If you have AML, your doctor will do blood tests during the first week to check for TLS.
- You will need to drink plenty of water. You may need to receive intravenous fluids at an outpatient clinic or hospital on specific days during the first 5 weeks if you have CLL or MCL, or 3 to 4 days if you have AML. You will also receive other medicines before starting VENCLEXTA to reduce your risk of TLS.
- Do not take any medicines that may have a strong interaction with VENCLEXTA.
- Sepsis (a blood infection in the entire body).

Some patients need to go to the hospital or may die from sepsis. Your doctor will closely monitor and treat you.

What VENCLEXTA is used for:

Chronic Lymphocytic Leukemia (CLL):

VENCLEXTA is used to treat adults with CLL. It is taken:

- **with another drug called obinutuzumab or ibrutinib.** This is used when CLL has not been treated before.

Or

- **with another drug called rituximab.** This is used when CLL has come back or has not responded to treatment.

Or

- **by itself** when CLL:
 - has a chromosome deletion and has come back or has not responded to treatment; or
 - has no chromosome deletion and other treatments are not available.

Mantle Cell Lymphoma (MCL):

VENCLEXTA is used to treat adults with MCL. It is taken **with another drug called ibrutinib** when:

- MCL has come back after it has been treated, or
- other treatments have not worked well enough or have stopped working.

Acute Myeloid Leukemia (AML):

VENCLEXTA is used to treat adults with AML:

- whose disease has not been treated before, and
- who are at least 75 years of age or have medical conditions that prevent them from having other types of chemotherapy.

For these patients, VENCLEXTA is taken with another drug. This could be either azacitidine or low-dose cytarabine.

How VENCLEXTA works:

VENCLEXTA works by blocking a protein in the body called “BCL-2”. This is a protein that helps cancer cells survive. Blocking this protein helps to kill and lower the number of cancer cells.

The ingredients in VENCLEXTA are:

Medicinal ingredient: venetoclax

Non-medicinal ingredients: calcium phosphate dibasic, colloidal silicon dioxide, copovidone, iron oxide yellow, polyethylene glycol, polysorbate 80, polyvinyl alcohol, sodium stearyl fumarate, talc and titanium oxide

The 50 mg tablet also contains iron oxide black and iron oxide red.

VENCLEXTA comes in the following dosage form:

Tablets: 10 mg, 50 mg, and 100 mg

Do not use VENCLEXTA if:

- you are allergic to venetoclax or to any of the other ingredients in VENCLEXTA or to any part of the container.
- you have CLL or MCL and are taking certain medicines when you start your treatment and during the time when your dose is gradually being increased (usually over 5 weeks). This is because these medicines may have a strong interaction with VENCLEXTA. Some of these medicines include:
 - clarithromycin, used for bacterial infections
 - itraconazole, ketoconazole, posaconazole or voriconazole, used for fungal infections
 - ritonavir, used for HIV infection

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VENCLEXTA. Talk about any health conditions or problems you may have, including if you:

- have low levels of neutrophils (a type of white blood cell), which is called neutropenia
- have kidney or liver problems
- have any signs or symptoms of infection such as fever, chills, cough, feeling weak or confused, or a painful or burning feeling when passing urine
- have recently received or are scheduled to receive a vaccine

Other warnings you should know about:Bleeding problems

If you are a patient with AML and are taking VENCLEXTA with azacitidine or low-dose cytarabine, you may be at higher risk for serious bleeding problems. These bleeding problems could lead to death. Your healthcare professional will monitor you for signs of bleeding problems.

Other cancers

During treatment with VENCLEXTA, a higher number of cases of certain types of non-melanoma skin cancer have been reported. Your healthcare professional will monitor you for the signs of skin cancer.

Tumour lysis syndrome

VENCLEXTA can cause a serious side effect called tumour lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. As cancer cells are destroyed, they release their contents, leading to high levels of certain chemicals (potassium, uric acid, phosphorus) and low levels of calcium in the blood. High or low levels of these chemicals can cause serious damage to your kidneys or other organs and may lead to death. TLS is most likely to occur in the first days or weeks of treatment with VENCLEXTA, as you increase your dose. It can also happen if you need to stop and restart your treatment.

If you have a higher number of cancer cells in your body, kidney problems, or an enlarged spleen, your risk for TLS may be higher. The changes in your blood that could lead to TLS may have no symptoms.

Having your blood tested is important in order to treat and prevent TLS. The symptoms below can be associated with rapid cell death or TLS:

- fever
- chills
- nausea (feeling sick to your stomach)
- vomiting
- confusion
- shortness of breath
- seizure
- irregular heartbeat
- dark or cloudy urine
- unusual tiredness
- muscle pain
- joint discomfort

If you notice any of these, call your doctor or nurse right away.

If you have CLL or MCL:

- Your doctor will do tests to check your risk of getting TLS before you start taking VENCLEXTA. Your doctor will also do blood tests during your first 5 weeks of treatment to check for TLS. It is important to keep your scheduled appointments for blood tests.
- Your doctor will give you other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS.
- You will need to drink plenty of water when taking VENCLEXTA to help reduce your risk of getting TLS.
 - For patients with CLL or MCL, follow the instructions about drinking water in the Quick Start Guide and as labelled inside the weekly wallet blister packs.
- Your doctor may hospitalize you before you start VENCLEXTA to give intravenous (IV) fluids into your vein, do blood tests, and check for TLS.

If you have AML:

- Your doctor may hospitalize you before you start your treatment. You may remain in hospital until 24 hours after you have reached the full VENCLEXTA dose. This will allow your healthcare professional to:
 - make sure that you have enough water/fluids,
 - give you medicines to prevent the build-up of uric acid in your body, and

- do blood tests before you start to take VENCLEXTA, while they increase your dose and when you start to take the full dose.

Adults 65 years of age and older:

Adults 65 years of age and older may be more likely to experience certain side effects when taking VENCLEXTA in combination with other medicinal products.

Children and adolescents less than 18 years of age:

It is not known if VENCLEXTA is safe or will work in children or adolescents less than 18 years of age.

Pregnancy, breastfeeding, birth control and fertility:

- VENCLEXTA should not be used during pregnancy. It may harm your unborn baby. Tell your doctor immediately if you become pregnant.
- Women who are able to become pregnant should have a pregnancy test before starting treatment with VENCLEXTA and should use effective birth control during treatment with VENCLEXTA and for at least 30 days after stopping treatment.
- Do not breastfeed while you are taking this medicine.
- VENCLEXTA may cause male infertility (low or no sperm count). This may affect your ability to father a child. Ask your doctor for advice before starting treatment with VENCLEXTA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Serious drug interactions can occur in patients with CLL and MCL at initiation and during the ramp-up phase if certain medications, called strong CYP3A inhibitors, are used with VENCLEXTA. These include:

- some medicines used to treat fungal infections – like itraconazole, ketoconazole, posaconazole and voriconazole
- some medicines used to treat bacterial infections like clarithromycin
- some medicines used to treat HIV infection like ritonavir

The following may also interact with VENCLEXTA:

- some medicines used to treat fungal infections – like fluconazole, itraconazole, ketoconazole, posaconazole and voriconazole
- some medicines used to treat bacterial infections – like ciprofloxacin, clarithromycin, erythromycin, nafcillin and rifampin
- some medicines used to prevent seizures or to treat epilepsy – like carbamazepine and phenytoin
- some medicines used to treat HIV infection – like efavirenz, etravirine, and ritonavir
- some medicines used to treat high blood pressure or heart-related chest pain (angina) – like bosentan, captopril, carvedilol, diltiazem, felodipine, ranolazine and verapamil

- a medicine used to treat a sleep disorder (narcolepsy) known as modafinil
- some herbal medicines – like St John’s wort and quercetin
- a blood thinner known as warfarin
- some medicines used to treat heart conditions – like amiodarone, digoxin, quinidine and ticagrelor
- an immunosuppressant drug known as cyclosporine
- DO NOT eat grapefruit (or drink its juice), Seville oranges (or marmalades) or starfruit while you are taking VENCLEXTA. These products may increase the amount of VENCLEXTA in your blood.

How to take VENCLEXTA:

- Always take VENCLEXTA exactly as your doctor tells you.
- Drink plenty of water when taking VENCLEXTA to help reduce your risk of getting TLS.
- Take the tablets with a meal and water at the same time each day.
- Swallow VENCLEXTA tablets whole. Do not chew, crush, or break the tablets.
- Your doses of VENCLEXTA may be lower in some cases, including if:
 - you have severe liver problems, or
 - you are taking certain medicines that can interact with VENCLEXTA.
- Your treatment may be interrupted or your dose lowered if you experience certain side effects.

For patients with CLL or MCL:

When starting VENCLEXTA:

- Read the Quick Start Guide that comes with your Starting Pack (which contains 4 weekly wallet blister packs).
- Drink 7 glasses of water each day (1.75 litres total). Start drinking this amount of water 2 days before your first dose. Continue to drink this amount each day. This is especially important on the 2 days leading up to your first dose and every time your dose is increased (days 1, 6 and 7 of each week). Follow the instructions about drinking water in the Quick Start Guide and as labelled inside the weekly wallet blister packs.
- Your doctor will do required blood testing prior to starting each week of the Starting Pack, as well as 6 to 8 hours and 24 hours after your first dose for each of the first 2 weeks of VENCLEXTA treatment. Do not take your next dose until your doctor knows the results of these blood tests and tells you it is safe to do so.
- Do not start a new dose unless your doctor tells you it is safe to do so.

Usual dose:

Your doctor will start VENCLEXTA at a low dose for 1 week. Your doctor will gradually increase the dose over the next 4 weeks to the full standard dose.

The usual dose is as follows:

- The starting dose is 20 mg (two 10 mg tablets) once a day for 7 days.
- The dose will be increased to 50 mg (one 50 mg tablet) once a day for 7 days.
- The dose will be increased to 100 mg (one 100 mg tablet) once a day for 7 days.
- The dose will be increased to 200 mg (two 100 mg tablets) once a day for 7 days.
- The dose will be increased to 400 mg (four 100 mg tablets) once a day.

For patients with CLL:

- If you are taking **VENCLEXTA in combination with obinutuzumab**:
 - You will start VENCLEXTA dosing after receiving your first cycle of obinutuzumab doses.
 - You will receive VENCLEXTA for 12 months.
- If you are taking **VENCLEXTA in combination with ibrutinib**:
 - You will start VENCLEXTA dosing after receiving your first 3 cycles of ibrutinib doses.
 - You will receive VENCLEXTA for approximately 12 months
- If you are taking **VENCLEXTA in combination with rituximab**:
 - You will start your rituximab after the first 5 weeks of VENCLEXTA.
 - You will receive VENCLEXTA for 2 years.
- If you are taking **VENCLEXTA alone**, you will stay on the 400 mg daily dose, which is the standard dose, for as long as necessary.

For patients with MCL:

- If you are taking **VENCLEXTA in combination with ibrutinib**:
 - You will start your ibrutinib on the first day that you start VENCLEXTA and continue to take it once daily.
 - You will receive VENCLEXTA and ibrutinib for approximately 2 years.

For patients with AML:

- Your healthcare professional will do blood tests before you start taking VENCLEXTA. Blood tests will be repeated regularly throughout your treatment.
- Your healthcare professional will ensure that you are well hydrated during the time when your dose is being increased. They may also give you other medicines to help prevent side effects during this time.

Usual dose for VENCLEXTA in combination with azacitidine:

Your doctor will start VENCLEXTA at a low dose. Your doctor will gradually increase the dose over the next 3 days to the full dose.

The usual dose is as follows:

- The starting dose is 100 mg (one 100 mg tablet) once a day for 1 day.
- The dose will be increased to 200 mg (two 100 mg tablets) once a day for 1 day.
- The dose will be increased to 400 mg (four 100 mg tablets) once a day for 1 day.
- You will continue to take 400 mg (four 100 mg tablets) per day for as long as necessary. This is the standard dose.

You will start your azacitidine on the same day that you start VENCLEXTA.

Usual dose for VENCLEXTA in combination with low-dose cytarabine:

Your doctor will start VENCLEXTA at a low dose. Your doctor will gradually increase the dose over the next 4 days to the full dose.

The usual dose is as follows:

- The starting dose is 100 mg (one 100 mg tablet) once a day for 1 day.
- The dose will be increased to 200 mg (two 100 mg tablets) once a day for 1 day.
- The dose will be increased to 400 mg (four 100 mg tablets) once a day for 1 day.
- The dose will be increased to 600 mg (six 100 mg tablets) once a day.
- You will continue to take 600 mg (six 100 mg tablets) per day for as long as necessary. This is the standard dose.

You will start your cytarabine on the same day that you start VENCLEXTA.

If you have questions about your dose of VENCLEXTA, talk to your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much VENCLEXTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

- If it has been less than 8 hours, take your dose as soon as possible.
- If it has been more than 8 hours, skip the missed dose and take the next dose at your usual time the next day.
- If you vomit after taking VENCLEXTA, do not take an extra dose. Take the next dose at your usual time the next day.
- If you are not sure, talk to your healthcare professional.

Possible side effects from using VENCLEXTA:

These are not all the possible side effects you may have when taking VENCLEXTA. If you experience any side effects not listed here, tell your healthcare professional.

- diarrhea or constipation
- nausea
- vomiting
- decreased appetite
- weight loss
- stomach pain
- heartburn
- upset stomach, indigestion
- swelling of your arms, legs, hands and feet
- muscle, back, bone and joint pain
- muscle spasms
- weakness
- mouth sores
- shortness of breath
- rash
- bruising
- skin infection
- itching
- dry skin
- fever
- headache
- dizziness
- feeling tired

- cough
- sore throat
- increased heart rate
- weak muscles, irregular heartbeat, and feeling tired (a result of low levels of magnesium in the blood)
- muscle cramps, joint and bone pain, itching, red eyes, numbness and tingling around the mouth, nausea, vomiting (a result of high levels of phosphate in the blood)

VENCLEXTA may cause abnormal exam and blood test results. Your doctor will do some tests before and during your treatment. The doctor will interpret the results. They will tell you if there are any abnormalities in your tests that might need treatment.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Leukopenia, Neutropenia, Lymphopenia (low levels of white blood cells): any signs of infection such as fever, chills, sweating, aches, pains, fatigue and flu-like symptoms		✓	
Anemia (low levels of red blood cells): fatigue, pale skin, shortness of breath, weakness		✓	
Thrombocytopenia (low levels of blood platelets): increases risk of bleeding or bruising		✓	
Sepsis and septic shock (a blood infection in the entire body): fever or dizziness, chills, high or very low body temperature, feel weak, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat			✓
Common			
Atrial fibrillation (irregular and rapid heartbeat/abnormal heart rhythm)		✓	
Atrial flutter (heart beats too fast but in a regular rhythm): palpitations, shortness of breath, dizziness, fainting		✓	
Cellulitis (skin infection): pain, tenderness, swelling, redness of the skin		✓	
Hemorrhage (bleeding problems): blood in stool, urine or eyes; vomiting blood; sudden and severe headache; nose bleeds; coughing up blood; purple spotted rash on the skin			✓
Hyperkalemia (high potassium levels in the blood): muscle fatigue, weakness, irregular heartbeat, nausea		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop this drug and get immediate medical help
	Only if severe	In all cases	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in ankles or legs, bluish colour to lips and skin, racing pulse or heart palpitations		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Pneumonia (infection of the lungs): chills, cough with or without mucus, fever, shortness of breath		✓	
Respiratory tract infection: runny nose, sore and scratchy throat, cough, sneezing, weak or loss of voice		✓	
Urinary tract infection: burning sensation during urination, low urine output despite feeling urge to urinate more often, pain in the pelvis or lower back, cloudy urine that may contain blood		✓	
Rare			
Tumour lysis syndrome (TLS; the sudden, rapid death of cancer cells due to the treatment): chills, confusion, dark or cloudy urine, fever, irregular heartbeat, joint discomfort, muscle pain, nausea, shortness of breath, seizure, tiredness, vomiting			✓
Multi-organ Dysfunction Syndrome (failure of multiple organs): failure of multiple organs (e.g., lung, kidney, heart) at the same time including passing less urine, difficulty breathing (including shortness of breath at			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop this drug and get immediate medical help
	Only if severe	In all cases	
rest or with activity), rapid breathing, wheezing or cough; yellowing of your skin and eyes, stomach pain or swelling, nausea or vomiting; chest pain (angina), shortness of breath, rapid, strong or irregular heartbeat, or if there is swelling of your ankles or feet			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 30°C.

Keep out of reach and sight of children.

If you want more information about VENCLEXTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.abbvie.ca); or by calling 1-888-704-8271.

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Date of Authorization: 2026-04-28

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