



 **Pr VENCLEXTA<sup>®</sup>**  
venetoclax tablets  
**AND YOU**

**FOR PATIENTS  
WITH PREVIOUSLY  
TREATED CLL**

**Information and tips  
to help you manage  
your treatment**

<sup>Pr</sup>VENCLEXTA<sup>®</sup> (venetoclax) is indicated in combination with rituximab for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy.

VENCLEXTA is indicated as monotherapy for the treatment of patients with CLL with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options.







# GETTING STARTED WITH VENCLEXTA

VENCLEXTA is used to treat patients with **chronic lymphocytic leukemia (CLL)**.

- VENCLEXTA is taken **with another drug called rituximab** when CLL has come back or has not responded to treatment.
- VENCLEXTA is taken **by itself** when CLL has a chromosome deletion and has come back or has not responded to treatment, OR when CLL has no chromosome deletion and other treatments are not available.

**To help you get started** on your treatment with VENCLEXTA, this guide will provide you with **important tips and information**, including brief descriptions on how VENCLEXTA works and **how to take your medication**.

As you go through treatment you will be **very well supported**. In addition to your healthcare professionals and your loved ones, the **AbbVie Care™ Support Program** offers you even more support with helpful information and services.



abbvie  
**care**™   
with you™  
Support Program





# ABBVIE CARE

WE'RE HERE FOR YOU, EVERY STEP OF THE WAY

**AbbVie Care is a support program** offering personalized services for people treated with VENCLEXTA and their care partners. As a program member, you will have access to a number of personalized services to help you during your treatment.



- Ongoing support services guide you and your care partner over the course of your treatment.
  - Your AbbVie Care Coach will call you within 24 hours of enrollment.



- Reimbursement services help you determine potential insurance coverage for your medication.
  - If your medication is covered through a provincial insurance plan, please be prepared to talk about your household income on this call.
  - When applicable, this information is used to determine deductibles for the plan.



- Pharmacy coordination services help you obtain your medication.
  - AbbVie Care can arrange to have your VENCLEXTA prescription delivered to your home or your doctor's office.



- Educational services help you learn about your condition and treatment.
  - You may receive support materials and tips and tricks to manage your condition and taking your medication.

**AbbVie Care** will stay in touch with your doctor to make sure that he/she is kept informed about each step of your treatment.



**Questions? Contact us.**  
[venclaxta@abbviecare.ca](mailto:venclaxta@abbviecare.ca)

**Call 1-844-346-6626**  
Monday to Friday,  
8 AM to 8 PM Eastern Time

**Visit: [venclaxta.abbviecare.ca](http://venclaxta.abbviecare.ca)**

Enter your 8-digit Drug Identification Number (DIN)  
to access the site, or simply use this number: 02458055

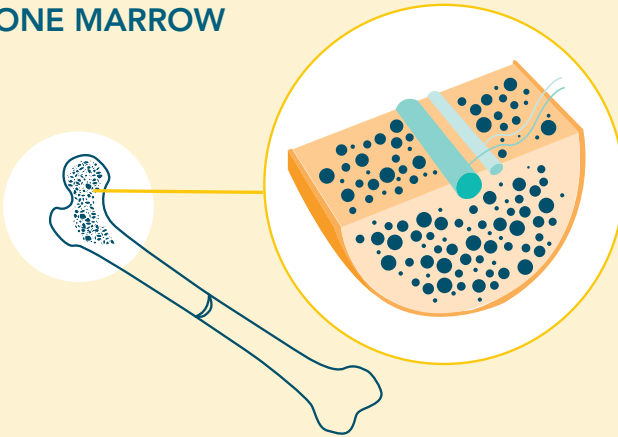
We look forward to offering our support.

# ABOUT CLL

CLL is **the most common type of adult leukemia** (blood cancer) in adults. Over 2,200 people in Canada are diagnosed with CLL each year.

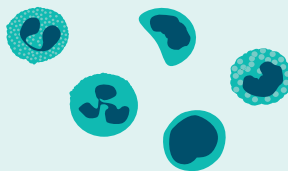
Blood cells develop from immature cells contained in bone marrow. There are different types of blood cells, including white blood cells that fight infections. In CLL, lymphocytes—a type of white blood cell—function abnormally and therefore do not fight infections very well.

## BONE MARROW



Blood cells develop from immature cells in bone marrow

## WHITE BLOOD CELL



Normal white blood cells fight infections





# HOW VENCLEXTA WORKS

VENCLEXTA works by blocking a protein in the body called "BCL-2". BCL-2 is a protein that helps the cancer cells survive. Blocking this protein helps to kill CLL cells and reduce the number of cancer cells in your body.

## INSIDE THE CLL CELL

VENCLEXTA blocks BCL-2 from trapping protein B (part of BCL-2 complex) which normally takes part in cell death.

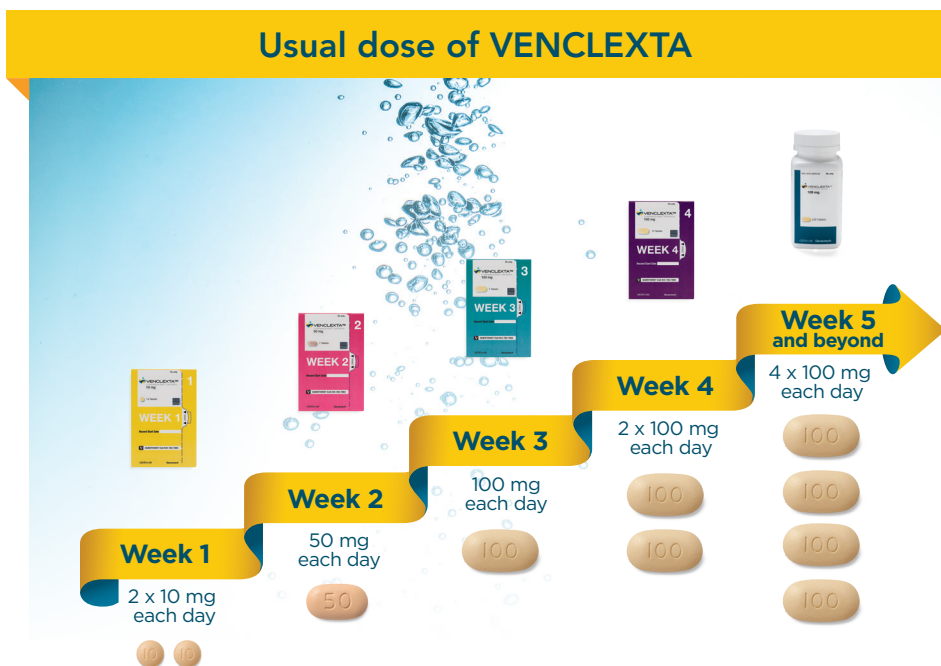
-  BCL-2 (Protein A)
-  VENCLEXTA
-  Protein B



# TAKING YOUR MEDICATION

Take VENCLEXTA exactly as you were told by your healthcare professionals. **Do not change your dose** unless your doctor tells you to do so.

The starting dose of VENCLEXTA is 20 mg (2 x 10 mg tablets) once a day for 7 days. Each week, the dose will increase until the standard dose of 400 mg (4 x 100 mg tablets) once a day is achieved. You can refer to the chart below to see how much VENCLEXTA to take each week.



## If you are taking VENCLEXTA alone:

You will stay on the standard 400 mg daily dose for as long as necessary.

## 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.

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.

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



# HOW TO TAKE VENCLEXTA



Take the tablets with a meal and water at the same time each day.



Swallow the tablets whole—you must not chew, crush or break them.



DO NOT eat grapefruit (or drink its juice), Seville oranges (or marmalades) or starfruit while you are taking VENCLEXTA as these products may increase the amount of VENCLEXTA in your blood.

## When starting VENCLEXTA:



- Read the **Quick Start Guide** that comes with your blister packs.
- Prior to starting each week, your doctor will do required blood testing, as well as 6 to 8 hours and 24 hours after your first dose for each of the first 2 weeks of treatment.
- **Do not** start a new dose unless your doctor tells you it is safe to do so.

**Drink plenty of water** when taking VENCLEXTA to help reduce your risk of getting tumour lysis syndrome (see the next page):

- **Drink 7 glasses of water** each day (1.75 litres total).
- Start drinking this amount of water **2 days before your first dose** and 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 your package of VENCLEXTA tablets.
- **Drink plenty of water when taking** VENCLEXTA. Speak to your healthcare professional about how much to hydrate after you finish the Starting Pack.



# TUMOUR LYSIS SYNDROME (TLS) AND VENCLEXTA

VENCLEXTA can cause a serious side effect called 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 (uric acid, potassium, 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 5 weeks of treatment. The changes in your blood that could lead to TLS may have no symptoms. The following may help reduce your risk of TLS: starting treatment with the 5-week ramp-up period; drinking plenty of water; having your blood checked during the first 5 weeks and not taking medicines that may have a strong interaction with VENCLEXTA.

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.

## YOU SHOULD NOT TAKE VENCLEXTA IF:

- You are allergic to any of the ingredients.
  - 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



# MEASURES TO HELP REDUCE YOUR RISK OF TLS

	Before you start taking VENCLEXTA	During treatment with VENCLEXTA
Your doctor will do tests to check your risk of getting TLS	✓	
Your doctor will do blood tests to check for TLS		✓ (during your first 5 weeks of treatment)
Your doctor will give you other medicines 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 (see page 14). Follow the instructions about drinking water in the Quick Start Guide and as labelled inside your package of VENCLEXTA.
- Your doctor may hospitalize you before you start VENCLEXTA to give intravenous (IV) fluids into your vein, do blood tests and check for TLS.

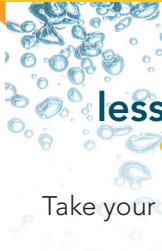
See page 14 for other warnings you should know about.

- You are taking certain medicines when you start your treatment and during the time when your dose is gradually being increased (usually over 5 weeks), because they may have a strong interaction with VENCLEXTA. Some of these medicines include:
  - Ketoconazole, voriconazole, itraconazole or posaconazole for fungal infections
  - Clarithromycin for bacterial infections
  - Ritonavir for HIV infection

**Talk to your healthcare professionals**

# IN CASE OF MISSED DOSE OR OVERDOSE

## If you miss a dose of VENCLEXTA



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

If you think you have taken  
too much VENCLEXTA,  
contact your healthcare  
professional, hospital emergency  
department or regional Poison  
Control Centre immediately, even  
if you have no symptoms.

# REMEMBERING TO TAKE YOUR MEDICATION

Forgetting to take a dose can happen to anyone. Something unexpected can happen leading to a change in your routine, you may run out of your medication or it can simply slip your mind. Whatever the reason may be, it is important to stick to your treatment exactly as prescribed by your doctor.

You should always talk to your healthcare professionals if you are unsure about anything. Forming good habits early is a helpful way to stick to your treatment plan.

Here are some other tips that may help you remember to take VENCLEXTA at the same time each day:

- Set a daily routine; combine it with a daily task
- Set up electronic reminders; this can be done via email or text
- Set an alarm; it can be set on your cell phone, pager or alarm clock
- Ask someone to remind you



## OTHER RELEVANT WARNINGS

- VENCLEXTA should only be prescribed by a doctor who is experienced in the use of anti-cancer drugs.
- VENCLEXTA is only available through specialty pharmacies and/or retail oncology pharmacies that are part of AbbVie's managed distribution program.
- VENCLEXTA can cause sepsis (a blood infection in the entire body). Some patients need to go to the hospital or may die from sepsis.
- During treatment with VENCLEXTA, a higher number of cases of certain types of non-melanoma skin cancer have been reported. Your doctor will monitor you for signs of skin cancer.
- 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.
- It is not known if VENCLEXTA is safe or will work in children or adolescents less than 18 years of age.
- 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 (contraception) 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.





# POSSIBLE SIDE EFFECTS

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

Side effects may include:

- Diarrhea or constipation
- Nausea
- Vomiting
- Stomach pain
- Swelling of your arms, legs, hands and feet
- Mouth sores
- Shortness of breath
- Rash
- Fever
- Headache
- Dizziness
- Feeling tired
- Cough
- Muscle, back, bone, neck and joint pain
- Itching

VENCLEXTA may cause abnormal 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.

**To help avoid side effects and ensure proper use, talk to your healthcare professionals 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.
- You have kidney or liver problems.
- You 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.
- You have recently received or are scheduled to receive a vaccine.

**Your healthcare professionals are there for you—tell them about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines**

# SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk to your healthcare provider	Stop taking VENCLEXTA and get immediate medical help
<b>VERY COMMON</b>		
<b>Leukopenia, Neutropenia, Lymphopenia</b> (low levels of white blood cells): any signs of infection such as fever, chills, sweating, aches, pains, fatigue and flu-like symptoms	✓	
<b>Anemia</b> (low levels of red blood cells): fatigue, pale skin, shortness of breath, weakness	✓	
<b>Thrombocytopenia</b> (low levels of blood platelets): increases risk of bleeding or bruising	✓	
<b>COMMON</b>		
<b>Hyperkalemia</b> (high potassium levels in the blood): muscle fatigue, weakness, irregular heartbeat, nausea	✓	
<b>Pneumonia</b> (infection of the lungs): chills, cough with or without mucus, fever, shortness of breath	✓	
<b>Respiratory tract infection:</b> runny nose, sore and scratchy throat, cough, sneezing, weak or loss of voice	✓	
<b>Urinary tract infection:</b> 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	✓	

Symptom/effect	Talk to your healthcare provider	Stop taking VENCLEXTA and get immediate medical help
<b>RARE</b>		
<b>Tumour lysis syndrome (TLS):</b> chills, confusion, dark or cloudy urine, fever, irregular heartbeat, joint discomfort, muscle pain, nausea, shortness of breath, seizure, tiredness, vomiting		✓
<b>Sepsis</b> (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		✓
<b>Multi-organ Dysfunction Syndrome</b> (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 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, talk to your healthcare professional.

**Talk to your doctor or nurse about any side effects you experience**

Store VENCLEXTA between 2 and 30°C.  
Keep out of reach and sight of children.

## SOME RESOURCES THAT CAN HELP YOU

It's important that you understand CLL and its management. To help you with this, we have put together some resources that can provide you with information, support and up-to-date CLL news.

CLL Patient Advocacy Group  
**cllpag.ca**

Lymphoma Canada  
**Lymphoma.ca**

Leukemia & Lymphoma Society of Canada  
**LLSCanada.org**

For any additional information regarding your treatment or condition, speak with your healthcare professionals.



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The resources suggested in this brochure do not imply an endorsement of or association with third-party organizations/websites and are provided for information purposes only. AbbVie is not responsible for content of non-AbbVie sites.







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