

STARTING VENCLEXTA[®]

YOU HAVE BEEN PRESCRIBED VENCLEXTA FOR THE
TREATMENT OF CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL)



abbvie

 **VENCLEXTA[™]**
venetoclax tablets

What does VENCLEXTA do?

VENCLEXTA blocks a protein called BCL-2, which helps cancer cells continue surviving. By blocking this protein, VENCLEXTA helps to kill and reduce the number of cancer cells and slows the disease from getting worse.

Taking VENCLEXTA

The starting dose of VENCLEXTA is 20 mg (2 x 10 mg tablets) once a day for 7 days. The dose will increase each week for the first 5 weeks of treatment until you reach the standard dose of 400 mg (4 x 100 mg tablets) once a day. The reason for this 5-week gradual dose increase phase is to reduce the risk of you getting a condition called tumour lysis syndrome (TLS), which is covered on the back of this guide. You will be prescribed a 4 week starter pack and following that, a bottle of tablets.



How to take VENCLEXTA

Before you start drink 6–8 glasses of water each day, starting 2 days before your first dose.

Take your first dose	6–8 hours*	Day 2	Day 3–7	Day 8
*Some patients may require more frequent blood tests. Your healthcare professional will explain when you need to have a blood test.				
<ul style="list-style-type: none">Take the tablets with a meal (or immediately after) and a glass of water at the same time each daySwallow the tablets whole, do not chew or crush themDO NOT eat grapefruit (or drink the juice), Seville oranges (or marmalades) or starfruit while taking VENCLEXTAIf you vomit after taking VENCLEXTA, DO NOT take an extra dose, take the next dose the next day as normal.	<ul style="list-style-type: none">Your healthcare professional will carry out your first blood test to check for any signs of tumour lysis syndrome (TLS)Ensure you drink 6–8 glasses of water before the end of the day to help prevent TLS.	<ul style="list-style-type: none">Your healthcare professional will carry out another blood test to check for any signs of TLSDO NOT take your second dose of VENCLEXTA on day 2 until your healthcare professional says it's OK to do soMaintain your normal daily water intake.	<ul style="list-style-type: none">Continue your daily medication at the same time every day with food and water (do not crush or chew the tablets)It is important that you continue to remain hydrated throughout your treatment, especially on Day 6 and Day 7 when you increase your dose.	<ul style="list-style-type: none">Your healthcare professional will advise you if it is appropriate for you to increase the dose following the results of your blood testRepeat this weekly process for each dose increase throughout the 5-week gradual dose increase phaseIf you start to show any symptoms of TLS, your healthcare professional will carry out another blood test sooner than scheduledEnsure you are drinking 6–8 glasses of water every day to help prevent TLS.
If you miss a dose of VENCLEXTA:				
<ul style="list-style-type: none">and it has been less than 8 hours – take your next dose as soon as possibleand it has been more than 8 hours – skip the missed dose and take your next dose as normal.				
If you think you have taken too much VENCLEXTA, immediately contact your healthcare professional, or go to hospital.				

What is tumour lysis syndrome (TLS)?

TLS is caused by the fast breakdown of cancer cells. As the cancer cells are destroyed, they can break open and what is inside the cancer cell (uric acid, potassium, phosphorus) gets into the blood.

This can lead to changes in kidney function, sudden kidney failure or even death. TLS is most likely to occur in the first 5 weeks of your treatment, which is why you follow the 5-week gradual dose increase phase when you start taking VENCLEXTA, to help prevent this from happening.

TLS can occur within 6–8 hours after the first dose and at each dose increase during the gradual dose increase phase. You should watch out for the following symptoms:

FEVER OR CHILLS	NAUSEA OR VOMITING	CONFUSION
SHORTNESS OF BREATH	IRREGULAR HEART BEAT	FITS OR SEIZURES
DARK OR CLOUDY URINE	UNUSUAL TIREDNESS	MUSCLE PAIN OR JOINT DISCOMFORT

If you experience any of these symptoms, inform your healthcare professional immediately.

If your healthcare professional notices signs of TLS, they will withhold your medication, monitor you and resume your medication at the same dose or a reduced dose once any signs or symptoms have resolved.

Assessing your risk of TLS

Before starting therapy with VENCLEXTA, your doctor will do some tests to work out your risk level for TLS.



You will need to have a blood test before you start and during the gradual dose increase phase of VENCLEXTA treatment. Your doctor will assess your risk of TLS and may give you blood tests more frequently if you are at high risk.



Your healthcare professional will also ask you drink 6–8 glasses of water (about 2 litres) daily two days before starting treatment with VENCLEXTA, and for a few days after each dose increase during the gradual dose increase phase. Staying hydrated is very important to help prevent TLS.



Your healthcare professional may also give you some other medicines to take before you start taking VENCLEXTA to reduce your risk of getting TLS.

If your healthcare professional thinks you are at high risk of getting TLS, they may also admit you to hospital before you start therapy with VENCLEXTA to give you intravenous fluids and do some further blood tests.

Side effects of VENCLEXTA

The most common side effects of VENCLEXTA are:

- feeling very tired • feeling sick • unusual weakness or lack of energy
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (symptoms of anaemia) • diarrhoea and vomiting • decreased appetite • dizziness • cough • shortness of breath, difficulty breathing or chest tightness

These side effects are usually mild and short-lived. Tell your doctor or pharmacist if you notice any and they worry you. Tell your doctor immediately if you have signs of an infection while taking VENCLEXTA.

For more information about VENCLEXTA you can read the Consumer Medicine Information, available at www.medsafe.govt.nz or www.venclexta.co.nz, or speak to your healthcare professional.

VENCLEXTA in combination with rituximab is fully funded for relapsed refractory chronic lymphocytic leukaemia (CLL). Special authority criteria apply. Normal prescription charges and doctor's fees apply.

IMPORTANT INFORMATION ABOUT VENCLEXTA®

VENCLEXTA is a prescription medicine containing venetoclax, which blocks a protein that helps cancer cells survive. VENCLEXTA is available as film-coated tablets of various strength (10 mg, 50 mg, 100 mg venetoclax). It is used, in combination with obinutuzumab to treat patients with chronic lymphocytic leukaemia (CLL) or Small Lymphocytic Lymphoma (SLL) that has not been treated before. VENCLEXTA is taken in combination with rituximab or alone, to treat patients with CLL or SLL when the condition comes back after it has already been treated. Your doctor will determine which treatment is suitable for your condition. Typically, you will begin treatment with VENCLEXTA at a low dose for 1 week. Your doctor will gradually increase your dose over the following four weeks to the full standard dose. **Use strictly as directed by your doctor. VENCLEXTA has risks and benefits.** You must not take it if you are allergic to venetoclax or to any of the inactive ingredients. Do not take it if you are taking certain medicines broken down in the liver, including: ketoconazole, posaconazole, voriconazole, itraconazole, clarithromycin or ritonavir. Do not drink grapefruit juice, or eat grapefruit, starfruit or Seville oranges or marmalades. Do not give VENCLEXTA to children and adolescents under 18 years of age. Do not take VENCLEXTA if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed. Tell your doctor if you have recently received or are scheduled for any vaccinations. **VENCLEXTA can cause tumour lysis syndrome (TLS)**, which is caused by the fast breakdown of cancer cells. TLS is a very serious side effect that can be fatal. TLS is most likely to occur when you are first starting treatment. Tell your doctor, nurse or pharmacist if you have or have had heart, kidney or liver problems. Let your healthcare provider know immediately if you experience: fever or chills, nausea or vomiting, confusion, shortness of breath, irregular heartbeat, dark or cloudy urine, fits or seizures, feeling unusually tired, or muscle pain or discomfort while on treatment with VENCLEXTA. Ensure you follow all your doctor's instructions carefully. Tell your doctor immediately if you have signs of an infection before or while taking VENCLEXTA, including fever, chills, feeling weak or confused, cough, or pain or burning feeling when passing urine. Some of the more common side effects of VENCLEXTA include feeling very tired, feeling sick, unusual weakness or lack of energy, tiredness, headaches, shortness of breath when exercising, dizziness and looking pale, diarrhoea, vomiting, decreased appetite, cough, difficulty breathing or chest tightness. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Some medicines and VENCLEXTA may interfere with each other, so tell your doctor if you are taking medicines containing any of the following: fluconazole, ciprofloxacin, erythromycin, azithromycin, nafcillin, rifampicin, carbamazepine, phenytoin, efavirenz, etravirine, captopril, carvedilol, felodipine, quinidine, ranolazine, bosentan, verapamil, diltiazem, modafinil, herbal medicines; St John's wort (*Hypericum perforatum*) and quercetin, warfarin, amiodarone, ticagrelor, digoxin, dronedarone, everolimus, sirolimus and ciclosporin. Tell any other doctors, pharmacists, dentists or surgeons treating you that you are taking VENCLEXTA and remind them before you start any new medicines.

If you have any questions about using VENCLEXTA, including its risks and benefits, how much to use, how and when to use it, or storage conditions, ask your healthcare professional and refer to the Consumer Medicine Information (CMI) available from www.medsafe.govt.nz or www.venclexta.co.nz. Ask your doctor if VENCLEXTA is right for you. Use strictly as directed. If symptoms continue, or you have side effects, see your doctor, pharmacist or healthcare professional.

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