

YOUR GUIDE TO CLL and treatment with VENCLEXTA + rituximab



INFORMATION AND TIPS TO HELP YOU MANAGE YOUR TREATMENT

This guide is intended only for patients prescribed VENCLEXTA + rituximab by a healthcare professional to treat relapsed or refractory CLL.

CLL: chronic lymphocytic leukaemia

The images in this guide do not feature real patients.

abbvie

ABOUT THIS GUIDE

Your doctor has prescribed VENCLEXTA + rituximab as the next stage of your treatment plan for CLL.

In this guide you'll learn about how this combination of treatments works, and how and when it is given. You'll also find out how to help minimise the risk of experiencing certain side effects, as well as how to manage them if they do occur.

This guide will also come with some treatment cards for you to fill in during the first few weeks of treatment. These are intended to be an easy way to remember what dose of VENCLEXTA you need to take each week and any other special instructions that your healthcare team has for you.



REMEMBER

Your healthcare team is your primary support every step of the way. They are the experts and can help you with any questions or concerns about your treatment. Always consult your doctor if you have any questions.

Your healthcare team contact details

Specialist: _____

Specialist nurse: _____

Hospital phone: _____

Out of hours phone: _____

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BEFORE STARTING TREATMENT

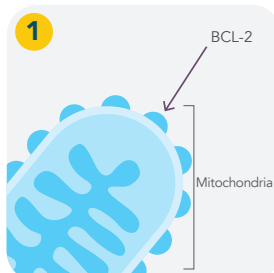
About CLL

CLL is a type of cancer that affects white blood cells called “B lymphocytes” and may also involve the lymph nodes, which are glands throughout the body that contain white blood cells.

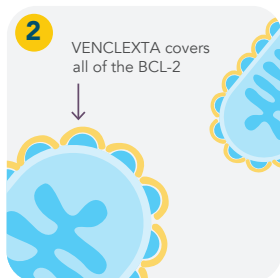
In CLL, the B lymphocytes multiply too quickly and live for too long, so that there are too many of them in the blood.

How VENCLEXTA works

VENCLEXTA works by blocking a protein in the body called “BCL-2” that helps cancer cells survive. It is therefore known as a “BCL-2 inhibitor”.



Inside the cancer cells, there are structures called “mitochondria” which help make energy. BCL-2 is found on the surface of these mitochondria.

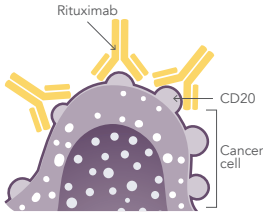


VENCLEXTA sticks to the BCL-2 and blocks it. Without the help of the BCL-2, the cancer cells die.

How rituximab works

Rituximab works in a different way to VENCLEXTA. It is known as a “CD20 antibody”.

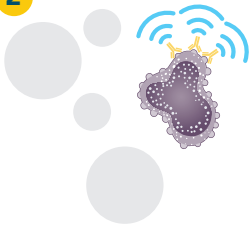
1



CD20 is a different type of protein (an “antigen”) found on the surface of some cells in the body, including CLL cancer cells.

Rituximab attaches to the CD20.

2



Once it attaches, it sends signals to the immune system, which arrives to attack and kill the cancer cells.

Rituximab is also thought to cause some direct damage to the cell it attaches to.



BEFORE YOU TAKE VENCLEXTA

Before you start your treatment your doctor will do blood tests and a scan (for example, a CT scan). Tell your doctor if you:

- have or have had heart, kidney or liver problems
- have or have had an infection
- if you recently received or are scheduled to receive a vaccine
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed

Tell your doctor or pharmacist if you have any allergies to any other medications, foods, preservatives or dyes. Tell your doctor about all the medicines you take, including prescription medicines and over the counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other causing serious side effects.

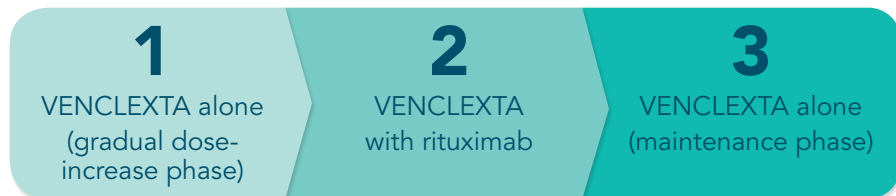
Medicines that can affect VENCLEXTA include:

Ketoconazole, posaconazole, voriconazole, itraconazole or fluconazole, used to treat fungal infections.	Clarithromycin, ciprofloxacin, erythromycin, azithromycin, nafcillin or rifampicin, used to treat bacterial infections.
Ritonavir, efavirenz, entravirine used to treat HCV (hepatitis C virus) or HIV infections.	Carbamazepine, phenytoin, used to prevent seizures or to treat epilepsy.
Captopril, carvedilol, felodipine, quinidine, ranolazine, bosentan, verapamil, diltiazem, medicines used to treat blood pressure, angina, or heart rhythm problems.	Modafinil, a medicine used to treat a sleep disorder known as narcolepsy.
Herbal medicines, St. John’s Wort (Hypericum perforatum) and quercetin. Warfarin, a medicine used to thin the blood.	Amiodarone, ticagrelor digoxin and dronedarone, medicines used to treat heart failure.
Everolimus and sirolimus used to treat cancer and patients who have had organ transplants.	Ciclosporin, a medicine used to suppress the immune system.

YOUR TREATMENT PLAN

Getting off to a good start on your VENCLEXTA + rituximab combination is important, but there's a lot to remember.

Firstly, there are 3 main phases of treatment that last about 2 years (24 months) in total:



Phase 1: VENCLEXTA alone (gradual dose-increase phase)

Your doctor will start you on a low dose of VENCLEXTA and gradually increase the amount you take until you are at the full dose. This phase usually lasts about 5 weeks, but your doctor may extend this gradual dose-increase period based on your response to the therapy.

DO NOT CHANGE YOUR DOSE unless your doctor tells you to.

This phase is important because certain side effects are more likely to occur when first starting treatment (see pages 11–14 for more information). By starting on a low dose and closely monitoring your response as the dose is increased, the risk of these side effects can be reduced.



Tablets not actual size

Phase 2: VENCLEXTA with rituximab

Once you've completed the gradual dose-increase phase, the rituximab treatment should then begin. You will continue taking the full dose of your VENCLEXTA treatment (4 x 100 mg tablets per day) throughout this phase, unless your doctor tells you to stop or reduces the dose temporarily.

While VENCLEXTA comes as an oral tablet that you can take at home, rituximab will be given to you each time by a healthcare professional via an "infusion". An infusion is where a medicine is fed gradually into your veins via an intravenous (IV) bag (similar to a "drip").



You will be given rituximab 6 times in total, once every 28 days (4 weeks). This is sometimes referred to as "6 cycles" of rituximab.

Your healthcare team will discuss with you about scheduling these infusion appointments and how long they will take.

Phase 3: VENCLEXTA alone (maintenance phase)

After your last rituximab infusion, you will continue taking the full dose of your VENCLEXTA treatment (4 x 100 mg tablets per day), unless your doctor tells you to stop or reduces the dose temporarily.

You do not need to keep taking VENCLEXTA forever. Once you reach a full 24 months since Day 1 your first rituximab infusion, you have finished treatment and your doctor will tell you to stop taking your VENCLEXTA tablets.

DURING TREATMENT

WHEN AND HOW TO TAKE VENCLEXTA

Take VENCLEXTA exactly as your doctor has prescribed. If you have questions about how to take VENCLEXTA, ask your doctor or pharmacist.



Take the tablets during or immediately after a meal, at about the same time every day. Taking it at the same time each day will have the best effect.



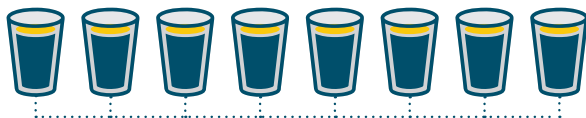
Swallow the tablets whole with a glass of water.



DO NOT chew, crush or break the tablets.

STAYING HYDRATED

It is important to stay hydrated and **drink plenty of water every day** when taking VENCLEXTA, but **especially** during particular days in the VENCLEXTA gradual dose-increase phase. This is because drinking plenty of water will reduce the risk of getting a particular side effect called tumour lysis syndrome (TLS), as the water will help remove cancer cell breakdown products from your blood through your urine (see pages 12–14 for more information).



6–8
glasses of water

Pay special attention and make sure you drink **at least 6–8 glasses of water on these days:**

- The two days before, and the day that you take your **first** VENCLEXTA dose
- The two days before, and the day you **increase** your VENCLEXTA dose.

OTHER IMPORTANT THINGS TO REMEMBER



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.



DO NOT change your dose unless your doctor tells you to.



DO NOT take VENCLEXTA if you are taking certain medicines when you start your treatment or during the ramp up phase because they may have a strong interaction with VENCLEXTA. Some of these medicines include:

- Ketoconazole, voriconazole, itraconazole or posaconazole, which are used to treat fungal infections.
- Clarithromycin, which is used to treat bacterial infections.
- Ritonavir, which is used to treat HIV or Hepatitis C virus infections.

It is important to tell your Doctor if you are taking these or any other medications, including prescription and over-the-counter medicines, vitamins and herbal supplements.



Your doctor may schedule blood tests during the first 5 weeks of treatment to check for side effects.



WHAT HAPPENS IF I DON'T TAKE THE CORRECT DOSE OF VENCLEXTA?



If you miss your dose at your scheduled dose time

If it has been
LESS THAN 8 HOURS

If it has been
MORE THAN 8 HOURS



Take your dose
as soon as possible.



Do not take the dose
that day. Take your 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 unsure, talk to your doctor or pharmacist.



If you think you (or anyone else) may have taken too much VENCLEXTA, immediately telephone your doctor or the National Poisons Centre (telephone 0800 764 766) or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

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, or you may run out of your medication, or it can simply slip your mind. Whatever the reason, it is important to stick to your treatment exactly as prescribed by your doctor.

You should always talk to your healthcare team 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, or combine it with a daily task
- Set up electronic reminders (e.g. via email or text)
- Set an alarm on your mobile phone, alarm clock or smart speaker
- Ask someone to remind you



POSSIBLE SIDE EFFECTS

Like all medicines, VENCLEXTA can cause side effects.

Not everyone will get them, but it's important to be aware of what they are so you can get help from your healthcare team right away if necessary.



If you are about to have any blood tests, tell your doctor that you are taking VENCLEXTA. It may interfere with the results of some tests.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- 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
- headache
- cough
- shortness of breath, difficulty breathing or chest tightness

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

SERIOUS SIDE EFFECTS & WHAT TO DO ABOUT THEM

Low white blood cell count (neutropenia)

Your doctor will check your blood count during treatment with VENCLEXTA. Low white blood cell count can increase your risk for infection. Some infections can be very serious. Signs of infection may include:

- fever
- chills
- feeling weak or confused
- cough
- pain or burning feeling when passing urine

Tumour Lysis Syndrome (TLS)

Some people having treatment for cancer can develop TLS, which is caused by the fast breakdown of cancer cells.

As the cancer cells are destroyed, they 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.

Having your blood tested is important in order to treat and prevent TLS. Before you start your treatment, your doctor will do blood tests and a scan (for example, a CT scan) to see if you are at risk of developing TLS.

It is important for you to keep your scheduled appointments for blood tests. The changes in your blood that could lead to TLS may have no symptoms.



If you have any questions or concerns about side effects, speak to your VENCLEXTA healthcare team.

SYMPTOMS OF TLS

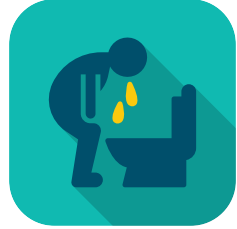
The following symptoms are associated with TLS.



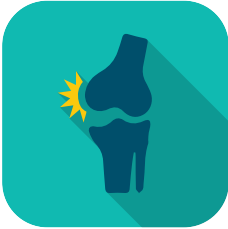
Fever or chills



Dark or cloudy urine



Nausea or vomiting



Muscle pain or
joint discomfort



Confusion



Unusual tiredness



Shortness of breath



Fits or seizures



Irregular heart beat

If you notice any of these, contact your doctor immediately.

MEASURES TO HELP REDUCE YOUR RISK OF TLS

Both you and your healthcare team need to work together to minimise the risk of TLS occurring.

What your healthcare team will do:



Before you start VENCLEXTA, your healthcare team will have assessed your risk of developing TLS and produced a plan to monitor you accordingly.



If they determine you are at risk of TLS, they may give you medicines to help prevent the build-up of uric acid in your body, a potential consequence of TLS.



As a precaution, your first dose of VENCLEXTA may be given in hospital, so that, if required, you can be given fluids, have blood tests, and be monitored. For some people at risk of TLS, your healthcare team may continue to give you some of your treatments in hospital.



Your VENCLEXTA healthcare team will tell you when you need to have your blood tested to check for initial signs of TLS.

What you need to do:



Make sure you keep your scheduled appointments for blood tests to check for signs of TLS, because the changes in your blood that could lead to TLS may have no noticeable symptoms.



Drink plenty of water.
See [page 7](#) for more details.

AFTER TREATMENT

STOPPING VENCLEXTA TREATMENT

VENCLEXTA is given for a fixed duration of time. It can be taken for up to 2 years after your first rituximab infusion, however your doctor will tell you if you need to finish treatment any earlier.

If your cancer gets worse, either while taking VENCLEXTA or at some timepoint after you have stopped taking it, your doctor will also discuss your other treatment options with you.



LIVING WELL WITH CLL

Looking after yourself

Cancer can be very strenuous, both physically and emotionally. Therefore, it's important to try to look after your yourself and your wellbeing as much as possible.



Nutrition – Good nutrition can help your body cope with your treatment and any side effects that occur. If you need some help in determining your dietary needs, your healthcare team may be able to help, or may refer you to a dietitian.



Stay hydrated – As mentioned earlier, staying hydrated is very important while taking VENCLEXTA, as this can help flush any cancer cell breakdown products from your blood through your urine and reduce the risk of side effects. See page 7 for details.



Staying active – Physical activity may help you feel better, less tired and has many other health benefits. However, everyone has different capabilities when it comes to exercising. Your doctor will be able to advise you on the amount and type of exercises that might suit you.



Dealing with stress and anxiety – Being diagnosed with cancer and the subsequent treatment of it can be a very stressful and overwhelming time in your life. If you are feeling depressed or anxious, it's important that you discuss this with your doctor in order to receive professional help.



However, there are many things you can also do yourself to try to minimise the stress in your life. These include:

- Looking beyond your cancer and making sure you connect with people and activities that are separate from it.
- Set yourself small, simple, manageable goals.
- Not isolating yourself: try to maintain your regular social interactions as much as possible.



Find support – Talking about your feelings can sometimes be difficult, but people often cope better with cancer when they're open with their partners, family members and friends about their condition and their fears and concerns. You may also find it easier to talk to people going through a similar experience via a dedicated support group. To find and join such a group, ask your doctor.

More information and support



If you have any concerns about this medicine, talk to your doctor, nurse or pharmacist.

Leukaemia & Blood Cancer New Zealand

website: www.leukaemia.org.nz

phone: 0800 15 10 15

email: info@leukaemia.org.nz

Medsafe Consumer Information

website: www.medsafe.govt.nz/Consumers/CMI/v/venclexta.pdf

AbbVie VENCLEXTA Website

To access VENCLEXTA Information on line, please go to www.venclexta.co.nz

MONITORING CARD

WEEK 1 – Beginning my treatment:



Remember to drink
**6–8 GLASSES OF
WATER** each day

Day 1

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When and where should I do my post-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Day 2

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Rest of the week

Additional instructions (if any): _____

This monitoring card is intended only for patients prescribed VENCLEXTA + rituximab by a healthcare professional to treat relapsed or refractory CLL. Abbvie Limited, PO Box 11437, Manners Street, Wellington 6142, New Zealand. NZ-VENC-190013. Prepared November 2019.

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venetoclax tablets

MONITORING CARD

WEEK 2 – Beginning my treatment:



Remember to drink
**6–8 GLASSES OF
WATER** each day

Day 1

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When and where should I do my post-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Day 2

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Rest of the week

Additional instructions (if any): _____

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MONITORING CARD

WEEK 3 – Beginning my treatment:



Remember to drink
**6–8 GLASSES OF
WATER** each day

Day 1

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When and where should I do my post-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Day 2

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Rest of the week

Additional instructions (if any): _____

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MONITORING CARD

WEEK 4 – Beginning my treatment:



Remember to drink
**6–8 GLASSES OF
WATER** each day

Day 1

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When and where should I do my post-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Day 2

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Rest of the week

Additional instructions (if any): _____

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MONITORING CARD

WEEK 5 – Beginning my treatment:



Remember to drink
**6–8 GLASSES OF
WATER** each day

Day 1

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When and where should I do my post-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Day 2

When and where should I do my pre-dose laboratory tests?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

When should I take my dose?

☐ Clinic ☐ Other location/address: _____

Date/time: _____ Phone: _____

Additional instructions (if any): _____

Rest of the week

Additional instructions (if any): _____

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venetoclax tablets

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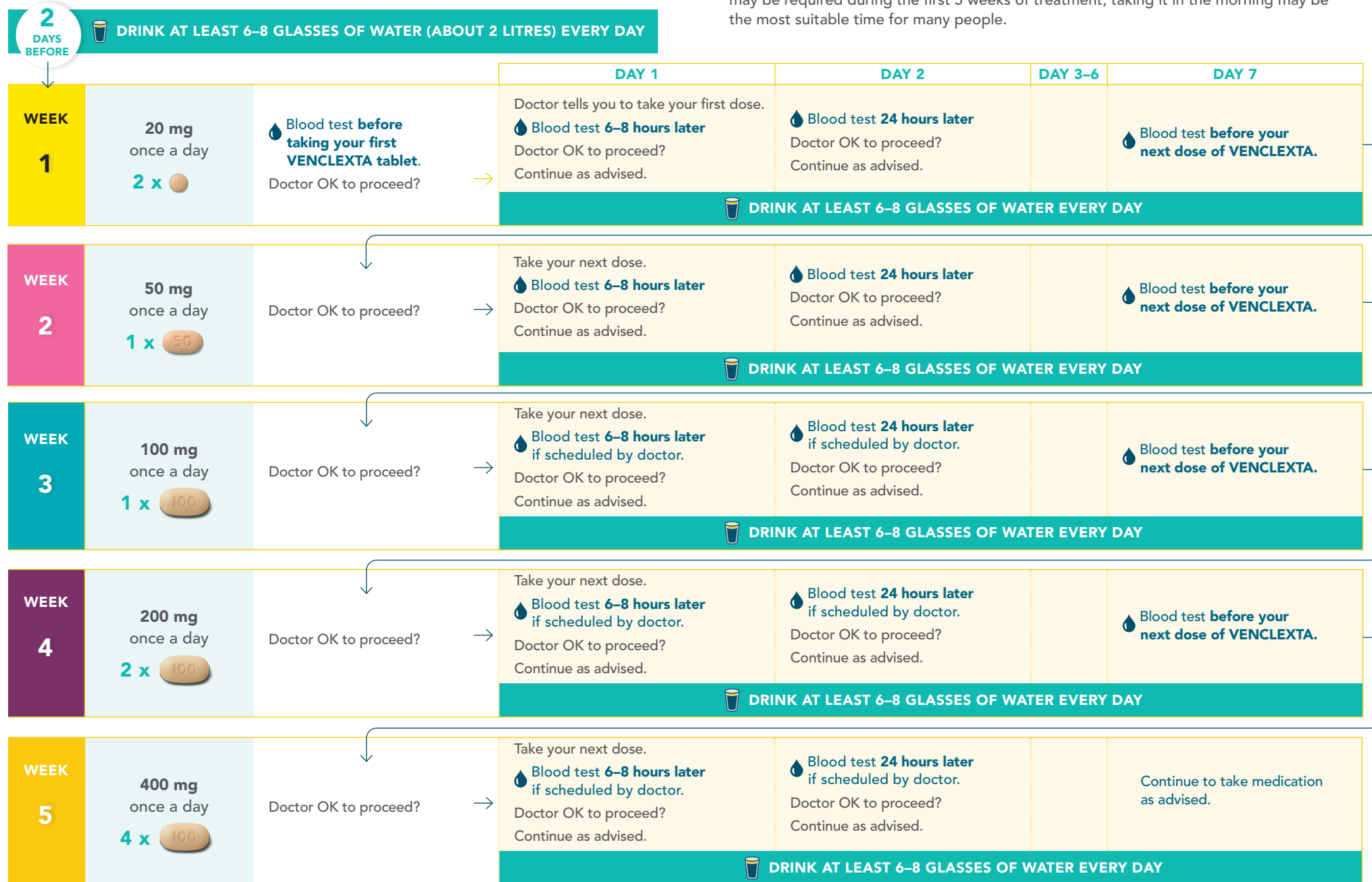
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YOUR FIRST 5 WEEKS – AT A GLANCE

This is only a guide. Your doctor will determine your dose, the amount of water you should drink and when you should have blood tests, the frequency of which may change to help prevent tumour lysis syndrome (TLS). You should always follow the advice of your healthcare team.



Before you start VENCLEXTA, or a new dose, you will need to:

- Wait for your healthcare team to give you the go-ahead to take it.

You should take your VENCLEXTA tablet(s) at the same time every day with a meal. Your doctor will tell you how many and at what time of day to take it. As follow-up blood tests may be required during the first 5 weeks of treatment, taking it in the morning may be the most suitable time for many people.

Please consult your doctor or healthcare team for further information and refer to the Consumer Medicine Information (CMI) for VENCLEXTA. The CMI is available online at www.medsafe.govt.nz or www.venclexta.co.nz.

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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