

#### **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.



### **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/SLL**

CLL and SLL are types of cancer that affect your blood.

**CLL** (chronic lymphocytic leukaemia) is a blood cancer that affects B cells. B cells are a type of white blood cell that helps fight infection. They are also called B lymphocytes.

**SLL (small lymphocytic lymphoma)** is closely related to CLL. However, SLL cancer cells are mostly found in the lymph nodes rather than in the blood and bone marrow.

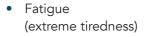
With cancer, healthy cells turn into abnormal, unhealthy cells that multiply too quickly and live for too long.

When normal cells are old or damaged, a process called **apoptosis** is triggered, causing those cells to self-destruct. Apoptosis is disrupted in some types of cancer causing the abnormal cells to build up in the body.

#### What are the signs and symptoms?

CLL and SLL are usually slow-growing types of cancer. Signs and symptoms often don't develop for years. When they do occur, they can include:

- Swollen lymph nodes (often in the neck, groin or under the arms)
- Sign





Weakness

Unexpected weight loss



ChillsFever





Night sweats



 Pain or sense of 'fullness' in the stomach

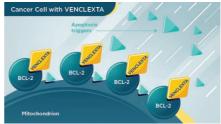


#### **How VENCLEXTA works**

VENCLEXTA contains the active ingredient venetoclax. It 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".

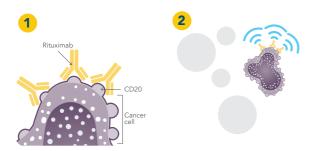
VENCLEXTA sticks to the BCL-2 and blocks it. Without the help of the BCL-2 protein, the cancer cells die.





#### How rituximab works

Rituximab works in a different way to VENCLEXTA. It works by binding to an antigen (CD20) on the surface of certain white blood cells known as B lymphocytes. It is the abnormally growing B lymphocytes that are responsible for certain types of lymphoma and leukaemia. During the process of binding to the antigen, the abnormal growth of the B lymphocytes is stopped.



#### **BEFORE YOU TAKE VENCLEXTA**

Tell your doctor, nurse or pharmacist if you:

- have any problems with your liver or kidneys
- are allergic to venetoclax, or any of the other ingredients of this medicine
- think you may have an infection
- have had any recent immunisations
- take any medicines for any other condition
- you are pregnant or think you might be pregnant
- are breastfeeding

Tell your doctor about all the medicines you take, including prescription medicines and over the counter medicines, vitamins, or supplements. Some medicines may interfere with VENCLEXTA and affect how it works.

#### Do not take VENCLEXTA if you are taking any of the following medicines:

- ketoconazole, posaconazole, voriconazole or itraconazole (medicines used to treat or prevent fungal infections)
- clarithromycin (a medicine used to treat infections caused by bacteria – antibiotic)
- ritonavir (a medicine used to treat HIV and hepatitis C)

#### This table shows medicines that can affect VENCLEXTA

Medicines that may increase the effect of VENCLEXTA include:	
ketoconazole, posaconazole, voriconazole, itraconazole, fluconazole	(medicines used to treat or prevent fungal infections)
clarithromycin, ciprofloxacin, erythromycin	(medicines used to treat infections caused by bacteria – antibiotic)
ritonavir	(a medicine used to treat HIV and hepatitis C)
diltiazem, verapamil, captopril	(medicines used to treat high blood pressure, angina and other heart conditions)
felodipine	(a medicine used to treat high blood pressure)
amiodarone, dronedarone, quinidine	(medicines used to treat certain heart conditions)

rifampicin	(a medicine used to treat tuberculosis and other serious infections)
carvedilol	(a medicine used to treat heart failure)
ciclosporin	(a medicine used to suppress the immune system to treat conditions like rheumatoid arthritis, nephrotic syndrome, psoriasis, transplant rejection)
quercetin	(a herbal product used for many conditions)
ranolazine	(a medicine used to treat angina)
ticagrelor	(a medicine used to help stop clots forming to reduce the chance of a heart attack, stroke)

Medicines that may reduce the effect of VENCLEXTA include:	
azithromycin, nafcillin	(medicines used to treat infections caused by bacteria - antibiotic)
rifampicin	(a medicine used to treat tuberculosis and other serious infections)
carbamazepine, phenytoin	(medicines used to prevent seizures, fits)
St John's wort	(a herbal product used to improve mood)
bosentan	(a medicine used to treat high blood pressure in the lungs)
efavirenz, etravirine	(a medicine used to treat HIV)
modafinil	(to treat certain sleep disorders)

Medicines that may have their effect increased when taken with VENCLEXTA include:	
warfarin	(a medicine used to thin the blood)
digoxin	(a medicine used to treat certain heart conditions)
everolimus	(a medicine used to treat certain cancers)
sirolimus	(a medicine used to help in organ transplants)

Foods that may increase the effect of VENCLEXTA include:	
grapefruit	(including as juice, jams, or marmalades)
Seville oranges	
star fruit	

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VENCLEXTA.

#### 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 – VENCLEXTA alone, VENCLEXTA in combination with rituximab and finally a maintenance period of VENCLEXTA alone.





Tablets not actual size

#### Phase 1 is 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 dose increase period based on your response to the therapy.

This phase of gradually increasing the dose is important because certain side effects are more likely to occur when first starting treatment. But by starting on a low dose, and having your response closely monitored by your doctor as the dose is increased, the risk of these side effects can be reduced.

Blood tests will be done before treatment starts and at each weekly dose increase.

Do not stop using this medicine or change your dose without checking with your doctor.

It is also important to stay hydrated during treatment with VENCLEXTA and drink at least 6-8 glasses (1.5 to 2 litres) of water a day, especially starting two days before and on the day of your first dose of VENCLEXTA and every time the dose is increased to reduce the risk of side effects.

#### Phase 2 is VENCLEXTA with rituximab

Once you have completed Phase 1, the rituximab infusions will then begin.

You will continue taking the full dose of your VENCLEXTA treatment throughout this phase, as directed by your doctor. That is usually four x 100 mg tablets per day, taken together as one dose, with food.



While VENCLEXTA comes as an oral tablet that you can take at home, rituximab is given by your nurse or doctor as an infusion through a needle placed in a vein (intravenous infusion) in your arm.

You will be given rituximab 6 times in total, once every 28 days. 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 is VENCLEXTA alone, a maintenance phase

After your last rituximab infusion, you will continue taking the full dose of your VENCLEXTA treatment (that is usually four x 100 mg tablets per day), for another 18 months unless your doctor tells you to stop or reduce the dose temporarily.

You do not need to keep taking VENCLEXTA forever. Once you reach a full 24 months since your first rituximab infusion, you will be able to stop VENCLEXTA.

It is important to remember to take your tablets every day as directed by your doctor until your doctor tells you to stop.

If your CLL returns, either while taking VENCLEXTA or at some time after you have stopped taking it, your doctor will also discuss your treatment options with you.



### **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.



Swallow the tablets whole with a full glass of water.



**DO NOT** chew, crush or break the tablets.

#### STAYING HYDRATED

It is important to stay hydrated when taking VENCLEXTA and drink about 6 to 8 glasses (1.5 to 2 litres) of water each day as instructed.

Make especially sure you drink your 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.



**6–8** glasses of water

#### 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** start any new medications without talking to your doctor, nurse, or pharmacist first. Certain medicines may affect how VENCLEXTA works and could cause serious side effects. See pages 4 and 5 for further details.

**DO** tell your Doctor if you are taking any other medications, including prescription and over-the-counter medicines, vitamins, or other supplements. See pages 4 and 5 for further details.



Your doctor will schedule blood tests before treatment starts and at each weekly dose increase to check for side effects. It is important that you keep these appointments.

Remind any doctor or dentist you visit that you are using VFNCI FXTA.



#### WHAT HAPPENS IF I MISS A DOSE?

It is important not to miss a dose of this medicine.



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, and take the next dose at the usual time the next day.



Skip the missed tablet(s) for 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 correct dose at your usual time the next day. If you are unsure, talk to your doctor, nurse 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

This list includes the less serious side effects of your medicine

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

- diarrhoea
- tummy pain
- constipation
- nausea (feeling sick)
- vomiting
- reduced appetite
- weight loss
- a sore inside the mouth
- looking pale

- · feeling tired
- having little or no energy
- shortness of breath when exercising
- feeling dizzy
- headache
- low blood pressure
- bleeding.

#### SERIOUS SIDE EFFECTS & WHAT TO DO ABOUT THEM

All medicines have some side effects. Sometimes they are serious so it is important to be aware of what they are so you can get help from your healthcare team right away if necessary. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

#### Neutropenia (low white blood cell count) and infections

You may experience a low number of neutrophils, a type of white blood cell - this can be severe and need treatment. Your doctor will check your blood counts during treatment with VENCLEXTA.

A low white blood count can increase your risk for infection. Some infections can be very serious or even fatal. Signs of infection may include:

- fever >38°C or chills
- feeling weak
- feeling confused

- congestion on the chest
- pain or burning when passing urine.

Your doctor will closely monitor and treat you right away if you have fever or any signs of infection during treatment with VENCLEXTA.

#### **Tumour Lysis Syndrome (TLS)**

cough, runny nose, sore throat

TLS is caused by the rapid breakdown of cancer cells resulting in high levels of certain chemicals and low levels of calcium circulating in the blood. This situation can cause serious damage to the kidneys as well as other organs in the body and can be fatal.

TLS is most likely to occur in the first weeks of your treatment, which is why you need to follow all your doctor's instructions carefully, especially when you start treatment with VFNCI FXTA.

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 to prevent and treat 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 until the situation becomes very serious.

Follow your doctor's instructions carefully, especially when you start treatment with VENCLEXTA. Tell your doctor, nurse or pharmacist if you have or have had **kidney problems** as this can increase the risk of TLS.

Take any additional medicines your doctor may prescribe to help prevent TLS (if you are at higher risk).

#### SYMPTOMS OF TLS

The following symptoms are associated with TLS. If you notice any of these, contact your doctor immediately or go straight to the Emergency Department at your nearest hospital.



#### 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.

Remember, it's important to stay hydrated when taking VENCLEXTA and drink 6 to 8 glasses (1.5 to 2 litres) of water each day as instructed. See page 9 for more details.

## **AFTER TREATMENT**

#### STOPPING VENCLEXTA TREATMENT

It is important to remember to take your tablets every day as directed by your doctor until your doctor tells you to stop.

If your CLL returns, either while taking VENCLEXTA or at some time after you have stopped taking it, your doctor will also discuss your treatment options with you.



## FOR PEOPLE WITH CLL/SLL WHO ARE PRESCRIBED VENCLEXTA. YOUR FIRST 5 WEEKS – AT A GLANCE

This is only a guide. Your healthcare professional (HCP) 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:

You should take your VENCLEXTA tablet(s) at the same time every

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

day with a meal. Your HCP will tell you how many and at what time of

# HELPFUL RESOURCES AND SUPPORT

# Go to the VENCLEXTA website www.venclexta.co.nz for these helpful resources and more:

- Short videos on the following:
  - YOUR VENCLEXTA 2-YEAR
     TREATMENT PLAN FOR
     RELAPSED OR REFRACTORY CLL
  - DURING YOUR VENCLEXTA TREATMENT
  - SIDE EFFECTS WITH VENCLEXTA
  - OVERVIEW FROM A NZ HAEMATOLOGIST
- An online version of this booklet
- INFORMATION FOR YOUR TREATMENT WITH VENCLEXTA Wallet Card – this is for you to note your details and show any doctor, nurse, dentist, pharmacist or other healthcare professional that you are taking VENCLEXTA before starting any new medicine.

#### Leukaemia & Blood Cancer New Zealand

website: www.leukaemia.org.nz

phone: 0800 15 10 15

email: info@leukaemia.org.nz

#### **Consumer Medicine Information**

website: abbv.ie/nz-ven-cmi



If you have any concerns about VENCLEXTA or CLL, please, talk to your doctor, nurse, or pharmacist. It is also important that you read the VENCLEXTA Consumer Medicine Information before starting treatment.







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#### **WEEK 5** – Beginning my treatment:

#### Day 1

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## LIVING WELL WITH CLL





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 9 for details.

Follow your doctor's instructions carefully, especially when you start treatment with VENCLEXTA, and refer to the VENCLEXTA Consumer Medicine Information for details regarding water intake.





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.

#### 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.



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 are open with their partners, family members and friends about their condition, 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 or nurse.

#### **NOTES**


VENCLEXTA in combination with rituximab is fully funded for relapsed/refractory chronic lymphocytic leukaemia (CLL). Special Authority criteria apply. Refer to the VENCLEXTA PHARMAC Special authority criteria at https://schedule.pharmac.govt.nz/SAForms.php. VENCLEXTA in combination with obinutuzumab for 1L CLL is not funded - a charge will apply. VENCLEXTA is not funded for acute myeloid leukaemia (AML) - a charge will apply.

VENCLEXTA® is supplied in New Zealand by: AbbVie Limited, 6th floor, 156-158 Victoria Street, Wellington, 6011, New Zealand Tel: 0800 900 030. **IMPORTANT INFORMATION ABOUT VENCLEXTA®** Venclexta is a prescription medicine containing venetoclax. Venclexta is available as film-coated tablets of various strength (10 mg, 50 mg, 100 mg venetoclax). It is used to treat adults with chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL). Venclexta is taken alone or in combination with other medicines. Your doctor will let you know which combination medicines, how to take them, and how long to take them. Typically, you will start treatment with Venclexta at a low dose. If you are taking Venclexta for CLL or SLL, your doctor will gradually increase your dose over 5 weeks up to the full 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. For CLL or SLL, do not take Venclexta if you are taking any of the following medicines: medicines used to treat or prevent fungal infections, including ketoconazole, posaconazole, voriconazole, itraconazole; clarithromycin (an antibiotic); or ritonavir (a medicine used to treat HIV and hepatitis C). 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. If you are a woman of child-bearing age, you must use a highly effective form of contraception during treatment with Venclexta and for at least 30 days after your last dose. Tell your doctor, nurse, or pharmacist if you have any kidney or liver problems; if you think you may have an infection; or if you recently received or are scheduled for any vaccinations. Do not stop using Venclexta of change the dose without checking with your doctor. **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. To help prevent TLS, it is important to stay hydrated and drink water every day when taking Venclexta. Particularly, starting two days before and on the day of your first dose of Venclexta and every time the dose is increased, drink 6 to 8 glasses (approximately 1.5-2 L total) of water each day. Let your healthcare provider know immediately if you experience: fever or chills, feeling sick or vomiting; being short of breath; feeling unusually tired; changes in your heart rate (slow, fast or irregular); your urine looks dark or cloudy; feeling confused; convulsions or fits; or pain in the muscles or joints while on treatment with Venclexta. Ensure you follow all your doctor's instructions carefully and keep all your appointments, including those for blood tests. You may experience a low number of neutrophils, a type of white blood cells - this can be severe and need treatment. Your doctor will check your blood counts during treatment with Venclexta. You may experience infections during treatment with Venclexta. Some infections can be very serious or even fatal. Your doctor will closely monitor and treat you right away if you have fever or any signs of infection during treatment with Venclexta. Tell your doctor immediately if you have signs of an infection before, or while taking Venclexta, including: fever or chills, feeling weak or confused, cough, runny nose, sore throat; congestion on the chest; or pain or burning when passing urine. Some of the less serious side effects of Venclexta include diarrhoea; tummy pain; constipation, nausea (feeling sick); vomiting; reduced appetite; weight loss; mouth sores; looking pale; feeling tired; having little or no energy; shortness of breath when exercising; feeling dizzy; headache; low blood pressure; bleeding. 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, diltiazem, verapamil, captopril, felodipine, dronedarone, amiodarone, quinidine, rifampicin, carvedilol, ciclosporin, quercetin, ranolazine, ticagrelor, azithromycin, nafcillin, carbamazepine, phenytoin, St John's wort (Hypericum perforatum), bosentan, efavirenz, etravirine, modafinil, warfarin, digoxin, everolimus, or sirolimus. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without prescription. 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 free phone 0800 900 030. 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. V7a. NZ-VENC-230018. TAPS BG2584. ONO0108. Prepared November 2023. ©2023 AbbVie. All rights reserved. AbbVie® is a registered trademark of AbbVie Inc. VENCLEXTA® is a registered trademark of AbbVie Manufacturing Management Unlimited Company. AbbVie Limited, PO Box 11437, Manners Street, Wellington 6142.



