

AML and getting started on VENCLEXTA[®] (venetoclax)

**in combination with azacitidine
or low-dose cytarabine**



VENCLEXTA, as part of combination therapy, is indicated for the treatment of adult patients with newly diagnosed AML (acute myeloid leukaemia) who are ineligible for intensive chemotherapy.

The images in this guide do not feature real patients.



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AN INTRODUCTION TO YOUR NEW TREATMENT

You have been given this booklet because your doctor has prescribed VENCLEXTA (venetoclax) in combination with azacitidine or low-dose cytarabine. This booklet is designed to help you understand your treatment with VENCLEXTA so you can take it as advised.

As you read through this booklet, make a note of any questions you have so you can share them with your healthcare team.





MY TREATMENT CONTACTS

Please complete the details below that are relevant to you.

Hospital/clinic: _____

Address: _____

Email: _____

Phone no: _____

After hours phone no: _____

Doctor's name: _____

Email: _____

Phone no: _____

After hours phone no: _____

Nurse's name: _____

Email: _____

Phone no: _____

After hours phone no: _____

Other contacts: _____

! REMEMBER

Once you've read through the booklet, if anything is still unclear, please talk to your healthcare team. You can also refer to the VENCLEXTA Consumer Medicine Information (CMI) leaflet for further information. Directions on how you can access the CMI are provided on page 22 of this booklet.

WHAT IS ACUTE MYELOID LEUKAEMIA (AML)?

AML is a condition where blood cells do not develop properly in the bone marrow. This results in a build-up of these immature cells in the blood and fewer red blood cells (that carry oxygen around the body), white blood cells (that fight infection) and/or platelets (that form clots when you are injured).

Without enough healthy white blood cells, your body's ability to fight infection is reduced. Without enough red blood cells and platelets, you may feel tired and bruise or bleed more easily.

WHAT IS VENCLEXTA?

VENCLEXTA is a cancer medicine that contains the active substance called 'venetoclax'. Your doctor has prescribed VENCLEXTA to treat your AML.

VENCLEXTA and combination therapy

Combination therapy means taking more than one treatment to treat a disease. VENCLEXTA is given in combination with azacitidine or low-dose cytarabine for the treatment of AML.

Your doctor can answer any questions you may have about azacitidine or low-dose cytarabine.

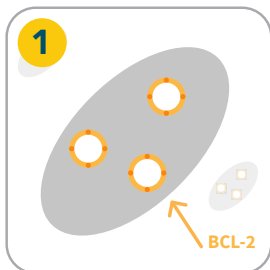


This booklet only contains information about VENCLEXTA.

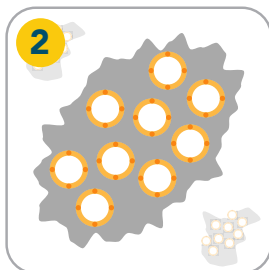
If you have questions about any of the other treatments you are taking, please speak to your healthcare team.



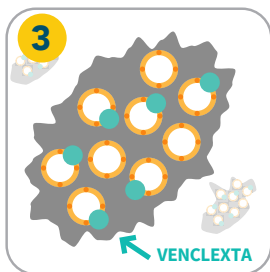
HOW VENCLEXTA WORKS



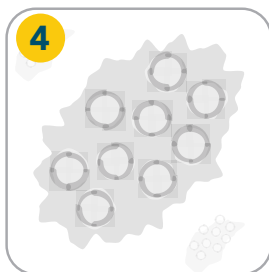
Normal cells in your body contain proteins called “B-cell lymphoma-2”, or “BCL-2” for short, which make sure cells undergo cell death at the right time.



AML cells make too much BCL-2, which helps AML cells survive.



VENCLEXTA works by blocking BCL-2 in cells that are producing too much of this protein.



Blocking this protein helps to kill and lower the number of AML cells.

Images are for illustrative purposes only.



VENCLEXTA is taken in tablet form, once a day.

Please speak to your healthcare team if you have any questions.

BEFORE VENCLEXTA TREATMENT BEGINS:

- It's important you stay well hydrated when taking VENCLEXTA.
- Make sure you drink plenty of water (6 to 8 glasses or 1.5 to 2 L per day) as instructed, throughout your treatment with VENCLEXTA, especially at the start of your treatment and every time your dose is increased during the gradual dose-increase phase.
- If you are in hospital, you might receive hydration through a drip.
- If your doctor has requested that you take other medications prior to VENCLEXTA, follow your doctor's instructions on how to take them.

IMPORTANCE OF BLOOD TESTS

VENCLEXTA breaks down the cancer cells in your body. As a result, there can be some changes to your blood chemistry that are important to monitor. Your healthcare team will arrange blood tests for you before you start VENCLEXTA and during the initial stages of treatment. It is important you keep to all your scheduled appointments.

WHAT HAPPENS DURING TREATMENT?

Depending on what your doctor advises, your treatment with VENCLEXTA will be either entirely as an outpatient (at home or in the day-stay unit at the hospital), or start as an inpatient in hospital with a transition to treatment at home. For your first few days of treatment your healthcare team will closely monitor how your treatment is working. One of the ways they do this is by taking blood tests.



It's important to keep an eye on how you're feeling so you can let your healthcare team know if you're experiencing any side effects. You'll find more information on possible side effects later in this booklet

THINGS YOU SHOULD KNOW BEFORE TAKING VENCLEXTA

OTHER MEDICINES AND VENCLEXTA

Tell your doctor or pharmacist if you take any of the following medicines as they can increase or decrease the effect of VENCLEXTA in your body:*

- Medicines for fungal infections – ketoconazole, posaconazole, voriconazole, itraconazole, or fluconazole
- Antibiotics to treat bacterial infections – clarithromycin, ciprofloxacin, erythromycin, azithromycin, or nafcillin
- Medicines for HIV and/or hepatitis C infections – efavirenz, etravirine; or ritonavir
- Medicines to treat raised blood pressure, angina or other heart conditions – diltiazem, verapamil, captopril, felodipine, dronedarone, amiodarone, quinidine, carvedilol, or ranolazine
- Medicine used to treat tuberculosis and other serious infections – rifampicin
- Medicine used to suppress the immune system – ciclosporin
- Herbal products – quercetin, or *St. John's wort*
- Medicine used to help stop clots forming to reduce the chance of a heart attack/stroke – ticagrelor
- Medicines to prevent seizures or to treat epilepsy – carbamazepine, or phenytoin
- Medicine used to treat high blood pressure in the lungs – bosentan
- Medicine to treat certain sleep disorders – modafinil

Your doctor may change your dose of VENCLEXTA if you are taking any of the above medicines or herbal products

*For a full list please see the Consumer Medicines Information.

Tell your doctor if you take any of the following medicines as VENCLEXTA may affect how they work:

- Medicine used to thin the blood – warfarin
- Medicine used to treat certain heart conditions – digoxin
- Medicine used to treat certain cancers – everolimus
- Medicine used to help in organ transplants – sirolimus



Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

These include:

- medicines without a prescription
- supplements
- vitamins
- herbal medicines



THINGS YOU SHOULD KNOW BEFORE TAKING VENCLEXTA

TALK TO YOUR HEALTHCARE TEAM BEFORE TAKING VENCLEXTA IF YOU:

- Have any problems with your liver or kidneys
- Think you may have an infection
- Have had any recent vaccinations
- Take any medicines for any other condition

Do not take VENCLEXTA if you are allergic to VENCLEXTA or any other ingredients in the product. Talk to your doctor or pharmacist if you are unsure.

TUMOUR LYSIS SYNDROME (TLS)

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.

The risk for TLS is usually the highest in the first days of treatment with VENCLEXTA, as you increase your dose.

To help prevent TLS, it is important to stay hydrated and drink water every day when taking VENCLEXTA.

Keep all your appointments, including those for your blood tests, since the changes in your blood that can lead to TLS may not have any symptoms until the situation becomes very serious. Take any additional medicines your doctor may prescribe to help prevent TLS.



It is recommended that you drink 6 to 8 glasses (approximately 1.5 to 2 litres total) of water each day, starting two days before and on the day of your first dose of VENCLEXTA, and every time the dose is increased.

HOW TO TAKE YOUR MEDICINE

STARTING TREATMENT

- Your healthcare team will start you on a low dose of VENCLEXTA and increase it each day until you reach your recommended dose (also called the dose increase or dose titration phase).
- You will have blood tests before and after each dose during the dose increase phase to monitor how your body is reacting.
- Your recommended dose depends on a number of things, including whether you are taking any other medicines, have any other health conditions and how you react to the treatment.
- Once you have reached your recommended dose, and your healthcare team is happy for you to do so, you will be able to continue VENCLEXTA treatment at home.

You should take VENCLEXTA as advised by your healthcare team at the prescribed dose. Do not change your dose or stop taking VENCLEXTA unless your healthcare team tells you to do so.

Two days before you start taking VENCLEXTA, drink at least 6 to 8 glasses of water each day and continue to do this throughout your treatment, especially each time your dose is increased.



Take VENCLEXTA once a day during a meal or immediately after a meal at about the same time every day.



AVOID grapefruit products, Seville oranges, or starfruit while taking VENCLEXTA. This includes:

- Eating them (including jams or marmalades)
- Drinking their juice
- Taking supplements that might contain them

They can increase the effect of VENCLEXTA in your body.






Swallow the tablets whole with a glass of water.



DO NOT chew, crush or break the tablets.

VENCLEXTA ORAL DOSING SCHEDULE

Day	VENCLEXTA once daily
1	Take 100 mg of VENCLEXTA. Your healthcare provider will also start you on azacitidine 75 mg/m ² (IV* or SC#), or cytarabine 20 mg/m ² (SC). 100 mg 
2	Take 200 mg of VENCLEXTA in combination with azacitidine, or cytarabine as determined by your healthcare provider. 200 mg 
3	Take 400 mg of VENCLEXTA in combination with azacitidine, or cytarabine as determined by your healthcare provider. 400 mg 

Day 4 and beyond (28-day cycle) VENCLEXTA once daily

In combination with azacitidine: Take 400 mg of VENCLEXTA in combination with azacitidine on **Days 1-7** of each 28-day cycle as determined by your healthcare provider.

400 mg 

OR

In combination with low-dose cytarabine: Take 600 mg of VENCLEXTA in combination with low-dose cytarabine on **Days 1-10** of each 28-day cycle as determined by your healthcare provider.

600 mg 

For illustrative purposes only, pills are not actual size.

***Intravenous (IV)** means within a vein. In this type of injection, the medication is injected directly into the vein.

#**Subcutaneous (SC)** means under the skin. In this type of injection, the medication is injected into the tissue layer between the skin and the muscle.

Your doctor may delay, decrease, or stop treatment for a period of time based on your lab work. This is common in treatment management. Be sure to ask your doctor if you have any questions about changes in dosing.



IF YOU MISS A DOSE

LESS THAN 8 HOURS

since the time you usually take your dose



TAKE THE MISSED TABLET(S)

as soon as you remember, and take the next dose at the usual time the next day.

MORE THAN 8 HOURS

since the time you usually take your dose



SKIP THE MISSED TABLET(S)

for that day and take your next tablets at the usual time the next day. Do NOT take a double dose to make up for the dose you missed.



IF YOU VOMIT AFTER TAKING VENCLEXTA

DO NOT TAKE ANY EXTRA TABLETS.

Just take the correct dose the next day at your usual time.



IF YOU TAKE TOO MUCH VENCLEXTA

IMMEDIATELY:

- Phone the National Poisons Centre (by calling 0800 764 766), and
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.
- You should do this even if there appear to be no signs of discomfort or poisoning.



Never take a double dose to make up for a missed dose.

Talk to your healthcare team if you have any questions about this. It is important that you take your medicine every day as instructed, until your doctor tells you to stop.



THINGS TO LOOK OUT FOR (possible side effects)

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

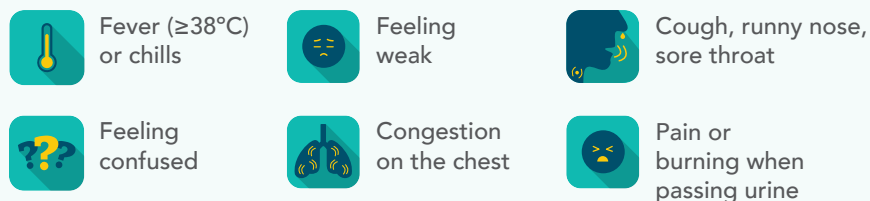
SERIOUS SIDE EFFECTS

The more serious side effects can include Tumour Lysis Syndrome (TLS), low white blood cell count (neutropenia) and infection.

Symptoms of TLS:



Symptoms of an infection:



INFECTIONS

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.

LESS SERIOUS SIDE EFFECTS

Speak to your doctor if you have any of these less serious side effects and they worry you:

- diarrhoea
- tummy pain
- constipation
- nausea (feeling sick)
- vomiting
- reduced appetite
- bleeding
- weight loss
- a sore inside the mouth
- low blood pressure
- looking pale
- feeling tired
- having little or no energy
- shortness of breath when exercising
- feeling dizzy
- headache

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

COMBINATION THERAPY (possible side effects)

When taking VENCLEXTA in combination with azacitidine or low-dose cytarabine, there may be additional possible side effects associated with these medicines. Speak to your healthcare team about other possible side effects that may occur as a result of your combination therapy.

VENCLEXTA has both risks and benefits. Always use VENCLEXTA according to your doctor's advice.

Please consult your doctor or healthcare team for further information or if you have any concerns or questions about using VENCLEXTA.

For important information, please refer to the Consumer Medicine Information (CMI) for your medication. CMIs are available from your pharmacist, or online at abbv.ie/nz-ven-cmi



Reporting side effects

If you get any side effects, talk to your healthcare team. This includes any possible side effects not listed in this booklet.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

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.

VENCLEXTA is not funded for acute myeloid leukaemia (AML).

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 acute myeloid leukaemia (AML). 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 AML, your doctor will gradually increase your dose up to the full dose over 3, or 4 days, depending on the combination medicine used. **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 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 or 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: ketoconazole, posaconazole, voriconazole, itraconazole, fluconazole, clarithromycin, ciprofloxacin, erythromycin, ritonavir, 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 abbv.ie/nz-ven-cmi 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. TAPS BG3342. NZ-VENA-230004. ON00128. September 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.

